

# Exhibit E

Suzanne Parisian, M.D.

Page 1

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

----- )  
IN RE: ETHICON, INC., PELVIC ) Master File No.  
REPAIR SYSTEM PRODUCTS ) 2:12-MD-02327  
LIABILITY LITIGATION ) MDL 2327  
 )  
 ) JOSEPH R. GOODWIN  
 ) U.S. DISTRICT JUDGE  
----- )  
 )  
Shirley Freeman, et al., )  
 )  
Plaintiffs, )  
 ) Case No.  
vs. ) 2:12-cv-00490  
 )  
 )  
ETHICON, INC., et al., )  
 )  
Defendants. )  
----- )

TVT-SECUR

Tuesday, March 8, 2016

- - -

Deposition of SUZANNE PARISIAN, M.D.,  
held at Marriott Tempe at the Buttes, 2000  
West Westcourt Way, Tempe, Arizona,  
commencing at 1:35 p.m., on the above date,  
before Alisa Smith, Arizona Certified Court  
Reporter.

- - -

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Suzanne Parisian, M.D.

Page 2			Page 4		
1	APPEARANCES:		1	EXHIBITS MARKED	
2			2		
3	WAGSTAFF & CARTMELL, LLP		3	EXHIBIT DESCRIPTION PAGE	
4	BY: NATE JONES, ESQUIRE		4	10 Composite re Prolift	30
5	4740 Grand Avenue, Suite 300		5	10A Amended Expert Report of John Miklos	31
6	Kansas City, Missouri 64112		6	11 United States Patent No. 6,287,316 B1	32
7	816.701.1100		7	12 Polypropylene Monofilament Kitted Mesh	36
8	njones@wcllp.com		8	Fabrics documents	
9	Representing Plaintiffs		9	13 Microbiological Safety document re	39
10			10	CODMAN ETHISORB Dura Patch	
11	AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC		11	14 ORDB 510(k) STERILITY REVIEW GUIDANCE	39
12	BY: BRYAN F. AYLSTOCK, ESQUIRE		12	7/3/97	
13	17 East Main Street, Suite 200		13	15 Dr. Parisian's Billing	60
14	Pensacola, Florida 32502		14	16 Gynecare TVT Patient Brochure	78
15	850.202.1010		15		
16	baylstock@awkolaw.com		16		
17	Representing Plaintiffs		17		
18			18		
19	BUTLER SNOW LLP		19		
20	By: WILLIAM M. GAGE, ESQUIRE		20		
21	Renaissance at Colony Park		21		
22	1020 Highland Colony Parkway, Suite 1400		22		
23	Ridgeland, Mississippi 39157		23		
24	601.948.5711		24		
25	william.gage@butlersnow.com		25		
	Representing Defendants Ethicon, Inc.,				
	and Johnson & Johnson				
Page 3			Page 5		
1	I N D E X		1	SUZANNE PARISIAN, M.D.,	
2	WITNESS PAGE		2	the witness herein, having been first duly sworn by	
3	SUZANNE PARISIAN, M.D.		3	the Certified Court Reporter, was examined and	
4	Direct Examination by Mr. Gage	5	4	testified as follows:	
5			5	DIRECT EXAMINATION	
6	* * * * *		6	BY MR. GAGE:	
7	EXHIBITS MARKED		7	Q. Good afternoon, Dr. Parisian.	
8			8	A. Good afternoon.	
9	EXHIBIT DESCRIPTION PAGE		9	Q. Before we get started with the Q and As, and	
10	1 Notice to Take Deposition of Suzanne	6	10	just so that the reader of this transcript will know	
11	Parisian		11	what has transpired, we are together in Phoenix,	
12	2 Dr. Parisian's Expert Witness Report	10	12	Arizona. It is in the afternoon.	
13	3 Dr. Parisian's CV	10	13	And this morning, from approximately 9 a.m.	
14	4 Legal Testimony History, Suzanne	11	14	local time until noon or somewhat after noon, I	
15	Parisian, M.D.		15	deposed you concerning your opinions in the federal	
16	5 List of Documents Provided or	11	16	multidistrict litigation concerning the Prolift+M	
17	Identified for Review in the above		17	device; correct?	
18	Referenced Lawsuit		18	A. Yes, sir.	
19	6 Binder labeled TVMS Docket, TVT Secur	19	19	Q. And during that deposition, I asked you a	
20	7 Composite exhibits re FDA	25	20	pretty significant number of questions about your	
21	communications		21	background, training, experience, what you have and	
22	8 Reclassification of Urogynecologic	26	22	have not done; correct?	
23	Surgical Mesh Instrumentation, FDA		23	A. Yes, sir.	
24	Questions		24	Q. And you would agree with me that nothing has	
25	9 Gynecare's TVT label	28	25	changed in the intervening hour since we concluded	

2 (Pages 2 to 5)

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<p style="text-align: right;">Page 6</p> <p>1 that deposition and the start of this deposition  2 that would cause your answers to change to the vast  3 majority of those questions; correct?  4 A. Yes, sir.  5 Q. So can we agree that it would be in our --  6 everyone's best interest of time management for me  7 not to re-ask those questions?  8 A. Yes, sir.  9 Q. Okay. And I would refer the reader of the  10 depo to the Prolift+M transcript of Dr. Parisian's  11 testimony in the event that they wish to read that  12 information.  13 (Whereupon, Exhibit No. 1 was marked  14 for identification.)  15 BY MR. GAGE:  16 Q. All right. Dr. Parisian, the first document  17 I'll hand you is the Notice to Take Deposition of  18 Suzanne Parisian, which is marked as Exhibit 1.  19 You've seen this document; correct?  20 A. This morning for the Prolift. I hadn't seen  21 it before.  22 Q. I think that's actually a combined depo  23 notice that pertains to both Prolift+M, and then  24 somewhere in there, it also pertains to TVT-Secur.  25 A. Okay. No, I hadn't seen it before.</p>	<p style="text-align: right;">Page 8</p> <p>1 MR. GAGE: Yes, with the  2 understanding -- with two -- two caveats. One is  3 plaintiffs' counsel, obviously, then agrees that  4 that deposition in the Garcia case can be used as  5 though it were taken in the federal MDL case.  6 MR. JONES: I don't think we're going  7 to have any objection against that.  8 MR. GAGE: Okay. And then secondly,  9 there are a few places where I'll need to ask  10 questions that would be repetitive of what was asked  11 in February of 2015, but it is being asked to  12 determine if the witness has done anything since --  13 MR. JONES: Sure.  14 MR. GAGE: -- February 2015. So --  15 but --  16 MR. JONES: But a general agreement.  17 MR. GAGE: Yeah, general agreement that  18 we don't intend to be duplicative of what you were  19 deposed about in February 2015.  20 MR. JONES: And just to add to that,  21 there were -- you did e-mail some specific topics  22 that you thought maybe it was a rough roadmap of  23 what you believe to be the topics that you felt were  24 new, or maybe a better word, not covered in the  25 February 2015 deposition that you had the right to</p>
<p style="text-align: right;">Page 7</p> <p>1 Q. And just so the record is clear, we're here  2 this afternoon not to discuss your Prolift+M  3 opinions but your TVT-Secur opinions?  4 A. Yes, sir. And there was another depo for  5 that once before too.  6 Q. Yes.  7 And the depo you're referring to is the  8 deposition in the Garcia versus Ethicon case;  9 correct?  10 A. Yes, sir.  11 Q. And I believe that deposition occurred in  12 February 2015; correct?  13 A. Sometime in 2015, yes, sir.  14 Q. Have you had a chance to read that  15 deposition?  16 A. I don't recall that I have.  17 Q. Okay.  18 MR. JONES: Real quick, William. I  19 won't take much of your time. And just for the  20 record, we do have an agreement that you will not be  21 covering the topics that were already covered in  22 that deposition that was taken of Dr. Parisian in  23 February 2015. And today's deposition will be  24 limited to topics that are new and outside of the  25 topics that were covered in that deposition.</p>	<p style="text-align: right;">Page 9</p> <p>1 ask about.  2 And if we need to refer to that at any  3 point, that might help, but generally speaking, not  4 going to cover same ground that was covered in the  5 February 2015 depo.  6 MR. GAGE: Yeah, generally speaking. I  7 mean, I did send you the -- I think there was a  8 question -- when I sent that e-mail, there was a  9 question as to whether I should even be permitted to  10 take any deposition of her on TVT-Secur.  11 So what I did was I went through the  12 report of Dr. Parisian in the MDL case and compared  13 it to the disclosure and the depo in Garcia in order  14 to assure myself there really was some differences,  15 because I was concerned maybe there were no  16 differences, in which case my position would be much  17 more difficult.  18 And by illustration, I showed you -- I  19 e-mailed and sent six topics, but trust me, you and  20 I are generally on the same agreement. I don't  21 want -- I've got limited time.  22 MR. JONES: When we get there, we'll  23 dig into it.  24 MR. GAGE: Exactly, exactly. I've got  25 limited time with her, and I need to focus on things</p>

3 (Pages 6 to 9)

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<p style="text-align: right;">Page 10</p> <p>1 that she's not --</p> <p>2 MR. JONES: Absolutely.</p> <p>3 MR. GAGE: It's good for me to find the</p> <p>4 stuff that she hasn't been asked about.</p> <p>5 (Whereupon, Exhibit No. 2 was marked</p> <p>6 for identification.)</p> <p>7 BY MR. GAGE:</p> <p>8 Q. All right. So, Dr. Parisian, I'm going to</p> <p>9 hand you what I have marked as Exhibit No. 2, and I</p> <p>10 believe this to be your TVT-Secur opinion in the MDL</p> <p>11 case, but please look that over and confirm that</p> <p>12 that is correct.</p> <p>13 A. Yes, sir. Yes, it is.</p> <p>14 (Whereupon, Exhibit No. 3 was marked</p> <p>15 for identification.)</p> <p>16 BY MR. GAGE:</p> <p>17 Q. All right. And, Dr. Parisian, I'll hand you</p> <p>18 what's been marked as Deposition Exhibit No. 3 to</p> <p>19 your TVT-Secur deposition. It also happens to be</p> <p>20 marked Deposition Exhibit No. 4 to the Prolift+M</p> <p>21 deposition.</p> <p>22 This is your current CV. Is that correct?</p> <p>23 A. Yes, sir.</p> <p>24 Q. And it is current and accurate, and there's</p> <p>25 nothing more to add or subtract from it; correct?</p>	<p style="text-align: right;">Page 12</p> <p>1 Q. All right. This will be Parisian Exhibit 5</p> <p>2 to your TVT-Secur deposition, and I understand this</p> <p>3 to be the list of documents provided or identified</p> <p>4 for review in the above-referenced lawsuit. Is that</p> <p>5 correct?</p> <p>6 A. That's what it states, yes, sir.</p> <p>7 Q. This is what we often refer to as the</p> <p>8 reliance list.</p> <p>9 Can you confirm that for me, that that is</p> <p>10 yours for the Secur case?</p> <p>11 A. Yes, sir.</p> <p>12 Q. All right. Dr. Parisian, with regard to</p> <p>13 your TVT-Secur report in the MDL, who typed that up?</p> <p>14 A. I did.</p> <p>15 Q. Can you tell me approximately when you</p> <p>16 started work on that report and when you completed</p> <p>17 work on it?</p> <p>18 A. No, sir. I don't have the -- I can't do</p> <p>19 that without the bill in front of me. I'll get you</p> <p>20 the bill.</p> <p>21 Q. All right. Let me just ask you, we know</p> <p>22 that you were deposed in the Garcia case in February</p> <p>23 of 2015; correct?</p> <p>24 A. Right. Um-hmm, yes.</p> <p>25 Q. That was about TVT-Secur; right?</p>
<p style="text-align: right;">Page 11</p> <p>1 A. Yes, sir.</p> <p>2 (Whereupon, Exhibit No. 4 was marked</p> <p>3 for identification.)</p> <p>4 BY MR. GAGE:</p> <p>5 Q. I'll also hand you Exhibit No. 4, which is</p> <p>6 also marked as Exhibit No. 5 in the Prolift+M case</p> <p>7 today, and this is the legal testimony history of</p> <p>8 Dr. Parisian. Is that correct?</p> <p>9 A. Yes, sir.</p> <p>10 Q. And that's a complete and accurate listing</p> <p>11 of your legal history over -- for the time period</p> <p>12 that's stated in that report; correct?</p> <p>13 A. Correct. It won't have Prolift+M on it.</p> <p>14 Q. I'm sorry?</p> <p>15 A. It won't have Prolift+M on it yet in terms</p> <p>16 of the depo.</p> <p>17 Q. Which was taken this morning?</p> <p>18 A. Right.</p> <p>19 (Whereupon, Exhibit No. 5 was marked</p> <p>20 for identification.)</p> <p>21 BY MR. GAGE:</p> <p>22 Q. And then, Dr. Parisian, I want to mark as</p> <p>23 Exhibit 5 --</p> <p>24 A. Well, the red one is 4, so that would be 5,</p> <p>25 yeah.</p>	<p style="text-align: right;">Page 13</p> <p>1 A. Right, but there was no report written at</p> <p>2 that time.</p> <p>3 Q. And that was the first and only -- well,</p> <p>4 that was the first case in which you had been</p> <p>5 designated as a TVT-Secur expert. Is that right?</p> <p>6 A. That's right.</p> <p>7 Q. Before that case, had you been retained to</p> <p>8 provide opinions on any Ethicon mesh device?</p> <p>9 A. No. No, I hadn't.</p> <p>10 Q. And can you -- and is it -- it is fair to</p> <p>11 say that you were retained by the plaintiffs in the</p> <p>12 MDL in the year 2015 to provide an expert opinion on</p> <p>13 TVT-Secur? Is that correct?</p> <p>14 A. Technically, I wasn't employed by the MDL to</p> <p>15 start with. I was with Clark, Love &amp; Hutson, just</p> <p>16 one case.</p> <p>17 Q. All right. So in the Garcia case, that's a</p> <p>18 Clark --</p> <p>19 A. Right.</p> <p>20 Q. -- Clark, Love case; correct?</p> <p>21 A. Right.</p> <p>22 Q. And who retained you in the MDL for</p> <p>23 TVT-Secur?</p> <p>24 A. I sort of got transferred, and I think</p> <p>25 Wagstaff &amp; Cartmell are the people that are the</p>

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<p style="text-align: right;">Page 14</p> <p>1 office I'm supposed to touch base with.  2 Q. Okay. So Clark, Love possibly got in touch  3 with Wagstaff &amp; Cartmell, and that's how you got  4 involved in the MDL litigation for TVT-Secur?  5 A. Something like that. I'm not sure if they  6 were in the MDL. I don't know. Somehow I ended up  7 in the MDL in a wave.  8 Q. And would that transfer have occurred after  9 your deposition in Garcia?  10 A. Yes.  11 Q. Not looking for specific dates. Just  12 ballpark.  13 Do you know when you first -- well, strike  14 that.  15 Is it fair to say that all the opinions you  16 intend to offer in this case are contained either in  17 your expert report that we've already marked or in  18 your TVT-Secur deposition in the Garcia case or in  19 the disclosure in the Garcia case?  20 A. Yes. As far as I know, I've tried to  21 capture them all in those three documents.  22 Q. All right. I don't have an extra copy of  23 your TVT-Secur deposition in Garcia or an extra  24 clean copy of your disclosure, so I'm not going to  25 mark those as exhibits.</p>	<p style="text-align: right;">Page 16</p> <p>1 MR. GAGE: Okay. All right. So I  2 don't have a copy of that.  3 MR. JONES: It may have been marked --  4 I don't think it was marked at her deposition,  5 though.  6 MR. GAGE: Okay. I do -- it seems like  7 I recall some discussion of it at her deposition,  8 though. I could be mistaken.  9 BY MR. GAGE:  10 Q. All right. So I've marked as Exhibit 5 here  11 for this deposition a notebook, a black binder  12 called TVMS docket at the top, and then below it, it  13 says, "TVT Secur."  14 And it says, "This belongs" -- on the cover  15 it says, "This belongs to Suzanne Parisian, MD," and  16 I've marked that as Exhibit 5.  17 Do you see that?  18 A. Yes, sir.  19 Q. And you gave that notebook to me or your  20 counsel before the start of this deposition;  21 correct?  22 A. Correct. And I --  23 MR. JONES: Just for the record, that  24 was also gave to you, Ethicon, at the February 2015  25 deposition as well.</p>
<p style="text-align: right;">Page 15</p> <p>1 But I'm explaining to whoever may read this  2 deposition, we all know what those documents are.  3 It was one disclosure that you filed -- or that was  4 filed on your behalf in Garcia about TVT-Secur, and  5 then of course there's one deposition transcript,  6 the actual date of which was February 12, 2015?  7 MR. JONES: Correct.  8 And we can get to the bottom of this  9 later, but my memory is that there might have been a  10 supplemental disclosure filed as well.  11 MR. GAGE: Yes.  12 BY MR. GAGE:  13 Q. Dr. Parisian, do you recall filing a  14 supplemental disclosure in the TVT -- for TVT-Secur  15 in the Garcia case?  16 A. I don't -- I don't recall that. Did I do  17 that?  18 MR. JONES: And that's my memory that  19 there was one filed in court. Again, if you have  20 it, if you don't have it, we can get to the bottom  21 of it later but --  22 MR. GAGE: Okay.  23 MR. JONES: -- my memory is that there  24 was a supplemental designation filed in that case  25 that's on that docket.</p>	<p style="text-align: right;">Page 17</p> <p>1 MR. GAGE: That was going to be my very  2 next question.  3 MR. JONES: Sorry.  4 MR. GAGE: That's all right.  5 THE WITNESS: Yes, it's the same  6 document that was given to you.  7 BY MR. GAGE:  8 Q. All right. So I'll ask the question.  9 Dr. Parisian, this notebook that's been  10 marked as Exhibit 5 at this deposition is exactly  11 the same notebook that was given to Ethicon's  12 counsel in the -- in your deposition in the Garcia  13 case back in February 2015?  14 A. Yes, sir.  15 Q. Okay. And this notebook contains a number  16 of highlights in it. I see, I think, a few  17 handwritten comments here and there. I certainly  18 see a lot of stickies -- yellow, purple, orange,  19 red.  20 Is it fair to say that all of the markings  21 on all the documents contained within Exhibit 5 are  22 your markings?  23 A. Yes.  24 Q. And you're the one that affixed the stickies  25 to the various documents?</p>



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<p style="text-align: right;">Page 18</p> <p>1 A. Correct.</p> <p>2 Q. Do the colors of the stickies or their</p> <p>3 organization or placing have any significance?</p> <p>4 A. No.</p> <p>5 Q. All right.</p> <p>6 A. And they were on at the other depo too, the</p> <p>7 stickies.</p> <p>8 Q. Okay. Good.</p> <p>9 We'll ask to have a copy made, if we don't</p> <p>10 already have this from the prior depo, complete with</p> <p>11 the highlighting and the stickies.</p> <p>12 A. Yes.</p> <p>13 Q. Dr. Parisian, there is a -- we have to make</p> <p>14 a change here. Let's get this very clear on the</p> <p>15 record.</p> <p>16 The black notebook entitled, "TVMS Docket,</p> <p>17 TVT Secur," the one that you and I have just been</p> <p>18 discussing, we're going to have to mark that</p> <p>19 Exhibit 6 --</p> <p>20 A. Okay.</p> <p>21 Q. -- not Exhibit 5.</p> <p>22 A. Okay.</p> <p>23 Q. That was my mistake. So we're going to mark</p> <p>24 that Exhibit 6, and I'm going to draw through the 5</p> <p>25 and mark the No. 6 on that exhibit sticker that's</p>	<p style="text-align: right;">Page 20</p> <p>1 same list.</p> <p>2 Q. Well, it's got a federal heading at the top</p> <p>3 of it --</p> <p>4 A. Right, right.</p> <p>5 Q. -- and by that time in February of 2015, you</p> <p>6 had not been retained to provide an expert opinion</p> <p>7 in the federal court proceeding for TVT-Secur, had</p> <p>8 you?</p> <p>9 A. Correct. They can change the heading. I'm</p> <p>10 talking about the list.</p> <p>11 Q. Gotcha.</p> <p>12 A. There should have been a reliance list at</p> <p>13 the depo. That's all.</p> <p>14 Q. Got it.</p> <p>15 Do you have a reliance list from Garcia</p> <p>16 other than just merely the contents of that notebook</p> <p>17 that's marked as Exhibit 6?</p> <p>18 A. No.</p> <p>19 Q. If I were to -- if I were to try to</p> <p>20 understand the universe of documents that you have</p> <p>21 reviewed for your TVT-Secur opinions, is it correct</p> <p>22 to say that there are two sources? One is the</p> <p>23 reliance list that's marked as Exhibit 5, and the</p> <p>24 second would be the notebook that's marked as</p> <p>25 Exhibit 6?</p>
<p style="text-align: right;">Page 19</p> <p>1 attached to the front of that notebook.</p> <p>2 (Whereupon, Exhibit No. 6 was marked</p> <p>3 for identification.)</p> <p>4 BY MR. GAGE:</p> <p>5 Q. So, Dr. Parisian, Exhibit 5 to this</p> <p>6 deposition is your reliance list for your federal</p> <p>7 MDL TVT-Secur report; correct?</p> <p>8 A. I think so. I did mention this morning that</p> <p>9 I saw Dr. Miklos' report, and I don't know if -- I</p> <p>10 don't see it on the reliance list. And so that</p> <p>11 would be a report that I have seen --</p> <p>12 Q. Okay.</p> <p>13 A. -- because you said, "Oh, that's for</p> <p>14 TVT-Secur."</p> <p>15 Q. Right.</p> <p>16 So -- and we'll -- we'll figure this out</p> <p>17 through the course of the next several questions,</p> <p>18 but what I'm -- did you prepare the reliance list</p> <p>19 that's marked as Exhibit 5?</p> <p>20 A. No.</p> <p>21 Q. Do you know who prepared that?</p> <p>22 A. No. No, I don't know who prepared it.</p> <p>23 Q. Have you ever seen that before?</p> <p>24 A. You know, I don't remember if that was at</p> <p>25 the same -- at the depo that we had for Garcia, the</p>	<p style="text-align: right;">Page 21</p> <p>1 MR. JONES: Objection.</p> <p>2 THE WITNESS: They should be similar,</p> <p>3 the book and the reliance list.</p> <p>4 BY MR. GAGE:</p> <p>5 Q. And you're speaking of Exhibit 5 and 6?</p> <p>6 A. Five and six, yeah.</p> <p>7 Q. Have you looked to see to the extent to</p> <p>8 which they're similar?</p> <p>9 A. No, no. But this was sent to me all put</p> <p>10 like this, so I assumed that the person who put the</p> <p>11 reliance list knew what they sent to me.</p> <p>12 Q. Okay. And when you were tapping your</p> <p>13 finger, you were tapping your finger on the notebook</p> <p>14 marked as Exhibit 6?</p> <p>15 A. Six, yes. And I'm just saying about five, I</p> <p>16 just never checked because I knew it was coming from</p> <p>17 someone else who was sending me a reliance list.</p> <p>18 Q. All right. So Exhibit No. 6 which is the</p> <p>19 notebook, was that supplied to you in the form in</p> <p>20 which it sits on this desk right now, i.e., in a</p> <p>21 hard copy notebook?</p> <p>22 A. Yes, sir. Stickies and all that are mine,</p> <p>23 but it was in a book.</p> <p>24 Q. Was that sent to you by the Clark --</p> <p>25 A. Yes.</p>

6 (Pages 18 to 21)

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<p style="text-align: right;">Page 22</p> <p>1 Q. -- Hutson firm?</p> <p>2 A. Yes.</p> <p>3 Q. Did you receive from that firm any disks or</p> <p>4 other electronic copies of documents for you to</p> <p>5 review?</p> <p>6 A. I don't recall. I didn't check it. This</p> <p>7 was -- this was the bulk of what I used, so I don't</p> <p>8 recall a CD. I don't -- I didn't look at my</p> <p>9 computer for it because I knew that this was what I</p> <p>10 had used primarily for the report.</p> <p>11 Q. Is it possible that you have additional</p> <p>12 TVT-Secur documents on your computer that aren't in</p> <p>13 the notebook?</p> <p>14 MR. JONES: Objection.</p> <p>15 THE WITNESS: They would have been</p> <p>16 things that are not confidential documents other</p> <p>17 than depositions. I don't know if there's depositions on it.</p> <p>18 That would be the only thing that would</p> <p>19 be confidential, because I would go and pull stuff</p> <p>20 up and put it on the computer.</p> <p>21 BY MR. GAGE:</p> <p>22 Q. All right. Do you have a list, or can you</p> <p>23 provide me with a list of the depositions that you would</p> <p>24 have -- well, strike that.</p> <p>25 On the reliance list, on the first page,</p>	<p style="text-align: right;">Page 24</p> <p>1 this morning on Prolift+M, you handed me several</p> <p>2 exhibit -- several stacks of additional documents</p> <p>3 that you had reviewed in conjunction with your</p> <p>4 Prolift+M documents -- Prolift+M opinions.</p> <p>5 Do you have any additional documents that</p> <p>6 you would like to hand me with regard to your</p> <p>7 TVT-Secur opinions that you have either gathered on</p> <p>8 your own or have received from some other source?</p> <p>9 A. Yes. Here they are.</p> <p>10 Q. All right. So --</p> <p>11 MR. JONES: Just for clarification, I</p> <p>12 think the 2008 FDA big document that was marked as</p> <p>13 Exhibit 6 earlier, I think that would probably also</p> <p>14 be applicable to her TVT-Secur.</p> <p>15 THE WITNESS: You mean the 522?</p> <p>16 MR. JONES: Yeah.</p> <p>17 MR. GAGE: Okay. So I'm glad you</p> <p>18 mentioned that, Nate.</p> <p>19 MR. JONES: Maybe not so much the other</p> <p>20 one, the reclassification.</p> <p>21 MR. GAGE: All right. So why don't</p> <p>22 we -- again, Nate, we don't ever know who's going to</p> <p>23 be reading this stuff. It could be, you know -- and</p> <p>24 you and I may remember it, but the people who are</p> <p>25 going to come along after us.</p>
<p style="text-align: right;">Page 23</p> <p>1 there's a section that calls -- that attempts to</p> <p>2 itemize the depositions that have been provided to</p> <p>3 you.</p> <p>4 Do you see that?</p> <p>5 A. Yes, sir.</p> <p>6 Q. Do you know if that list on page 1</p> <p>7 accurately matches the depositions you actually have</p> <p>8 reviewed and/or received for purposes of your</p> <p>9 TVT-Secur opinion?</p> <p>10 A. I don't know. I can do the same thing that</p> <p>11 I'm going to do for the Prolift+M and go look and</p> <p>12 see what's on my hard drive.</p> <p>13 Q. Okay. Good. That's where I was headed.</p> <p>14 I was going to ask you through your counsel</p> <p>15 if you would be willing to give us an itemization.</p> <p>16 I don't need anything fancy, but just an itemization</p> <p>17 that bears your signature so we know it has been</p> <p>18 approved by you --</p> <p>19 A. Right.</p> <p>20 Q. -- that would identify any depositions that</p> <p>21 you may have received and/or reviewed for purposes</p> <p>22 of your TVT-Secur opinion and which don't already</p> <p>23 appear on Exhibit 5.</p> <p>24 A. Yes.</p> <p>25 Q. And to your -- when I deposed you earlier</p>	<p style="text-align: right;">Page 25</p> <p>1 THE WITNESS: Yeah. The</p> <p>2 reclassification and the instruments, that would be</p> <p>3 another one. Do you have that? I think so.</p> <p>4 MR. GAGE: I'll pull that one too.</p> <p>5 MR. JONES: I think it's underneath</p> <p>6 your hand.</p> <p>7 (Whereupon, Exhibit No. 7 was marked</p> <p>8 for identification.)</p> <p>9 BY MR. GAGE:</p> <p>10 Q. So, Dr. Parisian, I'm handing you a stack of</p> <p>11 documents that you handed me this morning in</p> <p>12 conjunction with your Prolift+M which I understand</p> <p>13 to be documents that you obtained from counsel that</p> <p>14 pertain to FDA communications about surgical mesh.</p> <p>15 Is that correct?</p> <p>16 A. One of them does. This one here does. This</p> <p>17 one here is the -- the -- yeah, there you go.</p> <p>18 So, yes, Exhibit 7 would be what we had from</p> <p>19 this morning as Exhibit 6, and it's the FDA</p> <p>20 inter-discussion about what they were going to do</p> <p>21 with mesh.</p> <p>22 Q. Okay. And are you talking about Exhibit 7</p> <p>23 to this deposition, the stack of FDA documents,</p> <p>24 those are documents -- well, let me ask it like</p> <p>25 this: Are those documents that you reviewed --</p>

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<p style="text-align: right;">Page 26</p> <p>1 first reviewed after you wrote your TVT-Secur 2 report? 3 A. Yes. 4 Q. So those are just additional materials upon 5 which you may refer as you give your opinions on 6 TVT-Secur? 7 A. Right. And it's basically the internal 8 discussion of the FDA. 9 Q. And I think we discussed it during the 10 Prolift+M deposition that it is at least your 11 understanding that those documents were obtained by 12 plaintiffs' counsel through some form of request to 13 the FDA. Is that correct? 14 A. They look like the type received from a FOIA 15 request. They're redacted. 16 Q. And FOIA is F-O-I-A, Freedom of Information 17 Act, request? 18 A. Yes, sir. 19 (Whereupon, Exhibit No. 8 was marked 20 for identification.) 21 BY MR. GAGE: 22 Q. All right. And then the other document that 23 we need to mark is another stack of documents that 24 you handed me during the Prolift+M deposition this 25 morning where the title of it is "Reclassification</p>	<p style="text-align: right;">Page 28</p> <p>1 there any other documents or materials that you 2 reviewed or relied upon in preparing your expert 3 report in the federal MDL for TVT-Secur? 4 A. Well, I brought the Amended Miklos' report. 5 I brought also, if you look in there, the 2015 TVT 6 label even though -- 7 Q. Oh, I'm sorry. These documents in front of 8 me were part of what you handed me. Okay. 9 So let's mark those real quick. 10 (Whereupon, Exhibit No. 9 was marked 11 for identification.) 12 BY MR. GAGE: 13 Q. So, Dr. Parisian, I'm handing you a document 14 that I've marked as Exhibit No. 9, which is the 15 documents you handed me a few moments ago. 16 Can you tell me what that is? 17 A. This is -- I believe it's the 2015 -- yeah, 18 the Ethicon label. It's the most recent one I can 19 find. 20 Q. And that one has been changed from prior 21 versions; correct? 22 A. Yes, sir. 23 Q. Is it -- is it an adequate label? 24 A. No, it's not an adequate label. It's a 25 better label, but it's not an adequate label because</p>
<p style="text-align: right;">Page 27</p> <p>1 of Urogynecologic Surgical Mesh Instrumentation, FDA 2 Questions." We marked it as deposition Exhibit 7 to 3 your Prolift+M. It will now be deposition Exhibit 4 No. 8 to your TVT-Secur. 5 A. Yes. 6 Q. And is that the stack of documents that -- 7 that you handed me this morning from the Prolift+M? 8 A. Yes, sir. 9 Q. All right. And, Dr. Parisian, those -- I 10 see some -- some highlighting and a sticker on that. 11 Is that your highlighting and your sticker? 12 A. Yes, sir. Yes, sir. It's mine. 13 Q. All right. And if I remember correctly, 14 those were documents that you actually pulled, found 15 yourself. Is that correct? 16 A. Yes, sir. 17 Q. All right. Are there any additional 18 documents or reports that you have reviewed and/or 19 relied upon in conjunction with your Prolift+M 20 expert report in the federal MDL? 21 A. You mean the TVT-Secur? 22 Q. I'm sorry. Let me rephrase it. I knew that 23 was going to happen. 24 Dr. Parisian, apart from the documents that 25 we've already covered during this deposition, are</p>	<p style="text-align: right;">Page 29</p> <p>1 it's still not very specific to TVT. It's not 2 anything to do with TVT-S. It's just TVT, but it is 3 the current one right now. 4 Q. All right. Now, T- -- and you couldn't put 5 out a 2015 label for TVT-S because it's no longer on 6 the market? 7 A. That's right. It's off the market. 8 Q. All right. And where did you get that label 9 from? 10 A. I asked for it, and I got it from counsel 11 yesterday. 12 Q. All right. Are there any other documents 13 that you asked counsel to provide you? 14 A. Yes. The one that you had from the FDA, 15 that one we've all discussed. The other things all 16 there are mine. 17 Q. All right. And the ones -- what you're 18 referring to are the documents that are still in my 19 hand that I haven't marked as exhibits yet, and 20 we're going to go through those. 21 But your -- your -- your statement with 22 regard to these documents still in my hand are -- 23 these are documents that -- 24 A. They were in my folder, and I don't think 25 you had them necessarily, so I was giving them to</p>

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<p style="text-align: right;">Page 30</p> <p>1 you to be complete.  2 Q. Got it. All right. So let me look at this  3 really quick.  4 (Whereupon, Exhibit No. 10 was marked  5 for identification.)  6 BY MR. GAGE:  7 Q. Doctor, I'm handing you Parisian Exhibit 10.  8 What is that document, which you gave to me  9 earlier?  10 A. Actually, this is for Prolift. It should  11 have been for Prolift. Yeah, these are all  12 documents that I thought I had given to you this  13 morning that I didn't, yeah. So they really should  14 go with the one we had this morning.  15 Q. All right. So --  16 A. There is one document that applies to both  17 of these in there, and that's the Ethicon references  18 off of their Web site as to medical literature. And  19 that would have been what Ethicon would give a  20 physician for the medical literature.  21 But like you said, the product TVT is off  22 the market, TVT-S, Secur, and the rest are there for  23 pelvic organ prolapse.  24 Q. All right. I'm going to --  25 MR. GAGE: Let's just go off the record</p>	<p style="text-align: right;">Page 32</p> <p>1 this report to your opinions on TVT-Secur?  2 A. The physician opinions, because that's what  3 he talks about, and, also -- what was the  4 significance? I believe when I had the Garcia, I  5 talked about it, and I didn't see it listed on the  6 reliance list, and so I wanted to make sure you had  7 it.  8 Q. Okay. Have you for purposes of your MDL  9 report received any physician expert reports?  10 A. No.  11 Q. Have you received any expert reports from  12 anyone?  13 A. No.  14 Q. All right.  15 MR. GAGE: I'm going to mark as a  16 collective exhibit a number of documents that you  17 handed me that appear to pertain to patents. And  18 this is going to be Exhibit 11.  19 (Whereupon, Exhibit No. 11 was marked  20 for identification.)  21 BY MR. GAGE:  22 Q. All right. Dr. Parisian, you handed me  23 after the depo started the documents that are in  24 collective Exhibit No. 11.  25 Can you tell me what those are and what</p>
<p style="text-align: right;">Page 31</p> <p>1 for a second.  2 (Discussion off the record.)  3 BY MR. GAGE:  4 Q. So TVT-Secur -- so now that we're back in  5 the TVT-Secur deposition, Dr. Parisian, you handed  6 me a collection of documents which we were going  7 through after the deposition started.  8 One of them is an Amended Expert Report of  9 Dr. John Miklos in the Garcia case; correct?  10 A. Yes, sir.  11 (By agreement of the parties, the court  12 reporter was instructed after the deposition to mark  13 the Amended Expert Report of John Miklos in the  14 Garcia case as Exhibit 10A to the deposition in  15 order to correct a mistake made by defense counsel  16 in marking two different exhibits as Exhibit 10  17 during the deposition.)  18 (Whereupon, Exhibit No. 10A was marked  19 for identification.)  20 BY MR. GAGE:  21 Q. All right. And that was a document that you  22 had at the time you wrote -- or at the time that you  23 were deposed in the Garcia case; correct?  24 A. Yes, sir.  25 Q. And what was the significance, if any, of</p>	<p style="text-align: right;">Page 33</p> <p>1 their significance are to your opinions in the MDL?  2 A. I knew one of your questions was about the  3 TVT-S that you were going to ask me about  4 microporous versus heavy, and so I was trying to  5 find the definition of PROLENE.  6 And so that was what I actually went and got  7 this one patent from, and it's not the patent as  8 much as it defines what PROLENE is, and so that's  9 why I have that patent, and I put a yellow sticky  10 there, and it's highlighted.  11 Q. So the yellow highlighting and sticky are  12 your marks?  13 A. Right.  14 Q. Did you actually get that between the time  15 that we concluded the Prolift+M deposition and this  16 afternoon?  17 A. No, no. I had it. I got it last night  18 because I knew that was one of your questions.  19 Q. When you said, "I knew that that was one of  20 your questions," you were just speculating that I  21 was going to ask you that?  22 A. Yes, yes.  23 Q. Okay. And it turns out that I did ask you  24 that?  25 A. Yes, and I had gone and done my homework and</p>

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<p style="text-align: right;">Page 34</p> <p>1 I want -- because it's hard to have a definition of  2 PROLENE and so -- because, you know, it's a  3 pre-amendment product, and it's been out there, and  4 so I've been trying to find something that would  5 define it to look at, you know, the weight and the  6 porosity.  7 So I found something, and so -- and then as  8 I went and looked for the patent, I went and got the  9 trademarks, just to kind of get -- put me on the  10 right track as time-wise, so that's what this is  11 about.  12 Q. Is it your understanding that the TVT-Secur  13 is made of the same mesh that's contained within the  14 documents marked as Exhibit 11?  15 A. It's not -- it's made of the same -- no.  16 This is -- this is different. The mesh that it's  17 made out of is the PROLENE here where it's talking  18 about the standard PROLENE. So it's made of this  19 mesh, which is the PROLENE.  20 Q. All right. And when you say -- you're  21 pointing to page 4 of this document --  22 A. Right.  23 Q. -- that references PROLENE mesh manufactured  24 by Ethicon, Inc., and it gives an average  25 flexibility, burst strength, pore size, and</p>	<p style="text-align: right;">Page 36</p> <p>1 I haven't seen a specification where the company  2 defines PROLENE, but I was trying to put my finger  3 on something that the company defines.  4 BY MR. GAGE:  5 Q. Okay. So --  6 A. It's in their patent defining what PROLENE  7 is, and so that's where I will -- you know, I would  8 just say in terms of the porosity and stuff.  9 So I have no doubt that the TVT-S is made  10 out of PROLENE, and PROLENE has been on the market  11 since the '70s, before -- before it was even 510(k)  12 cleared.  13 (Whereupon, Exhibit No. 12 was marked  14 for identification.)  15 BY MR. GAGE:  16 Q. All right. Dr. Parisian, I'm handing you a  17 collection of documents that were already tabbed as  18 collective Exhibit 12.  19 Can you tell me what those documents are and  20 what is their significance, if any, to your  21 TVT-Secur opinion?  22 A. Well, it's showing different -- if you're  23 manufacturing, you want to get mesh, polypropylene  24 filament mesh. These are the types of documents --  25 one of them is a guidance document. I don't know if</p>
<p style="text-align: right;">Page 35</p> <p>1 thickness; correct?  2 A. Correct.  3 And so the company is defining what PROLENE  4 is so I wanted to -- because it's kind of hard to  5 pin it down, and so I believe TVT-Secur is made out  6 of PROLENE, which is your basic garden variety  7 PROLENE, and so -- and it's 49 percent porosity and  8 trying to -- so I was trying to hone in on it.  9 Q. Okay. And I think you and I were discussing  10 this earlier, and we got a little confused.  11 You understand there's PROLENE material and  12 there's PROLENE mesh?  13 A. Sure, I know about PROLENE suture. I mean,  14 yes, I can go through PROLENE, but it's all from the  15 resin, which is a polypropylene resin that they can  16 make it into suture, they can make it into fibers,  17 and they extrude it and make it into mesh.  18 Q. Okay. So for purposes of the TVT-Secur  19 opinion that you have, is it your understanding, for  20 example, that the average flexibility, the burst  21 strength, the pore size, and the thickness of the  22 TVT-Secur is that which is found on page 4 of this  23 document that's marked as Exhibit 11?  24 MR. JONES: Objection.  25 THE WITNESS: You know, I don't know.</p>	<p style="text-align: right;">Page 37</p> <p>1 you're familiar with that.  2 But these are mesh patterns. See how the  3 mesh -- so people can get it woven, and they have  4 different -- I was trying to hone in on the PROLENE.  5 Nobody calls one of these PROLENE, but you can look  6 at the mesh pattern and try to figure out the size.  7 Q. Were you able to determine, from looking at  8 Exhibit 12, which of the various lines of data  9 pertain to the mesh in TVT-Secur, if any?  10 A. This -- this one here looks the most like  11 it, but I'm not the mesh expert. I mean, that would  12 be like 100 weight. This is the right weight,  13 thickness, so it would be something like in this  14 here.  15 Q. And the line that you're referring to is the  16 line that has PPKM 601?  17 A. Yeah. But, again, I'm not your mesh expert,  18 so . . .  19 Q. All right. And then -- and did you gather  20 this document on your own?  21 A. Yes, sir.  22 Q. Was this just for your own general guideline  23 information?  24 A. Yes, sir.  25 Q. I take it you don't have any -- you're not</p>

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<p style="text-align: right;">Page 38</p> <p>1 rendering any specific opinions about this document?</p> <p>2 A. No.</p> <p>3 Q. Okay. And then since it is a composite</p> <p>4 exhibit, it's got something from surgicalmesh.com</p> <p>5 behind it.</p> <p>6 A. Right. And so I was just going and looking</p> <p>7 at sources of polypropylene mesh. This is the</p> <p>8 guidance document which is -- we haven't discussed</p> <p>9 that yet.</p> <p>10 Q. All right. So the final document contained</p> <p>11 within composite Exhibit 12 is a guidance for</p> <p>12 preparation of premarket notification application</p> <p>13 for surgical mesh dated March 2, 1999; right?</p> <p>14 A. Right.</p> <p>15 Q. And that's an FDA guidance; correct?</p> <p>16 A. That's right.</p> <p>17 Q. Did that ever become final?</p> <p>18 A. You know, I don't think it has. I've never</p> <p>19 seen one after 1999. I know they've had a thing for</p> <p>20 IDEs for SUI devices, and they're going to do a PMA,</p> <p>21 but I don't think I've seen a later version.</p> <p>22 Q. Again, the reason you handed me that</p> <p>23 document is because it was a document that you went</p> <p>24 and got on your own -- is that correct? --</p> <p>25 A. Yes, sir.</p>	<p style="text-align: right;">Page 40</p> <p>1 BY MR. GAGE:</p> <p>2 Q. All right. And then the final document -- I</p> <p>3 thought I was finished, but I had one more --</p> <p>4 Parisian Exhibit No. 14.</p> <p>5 Dr. Parisian, that document has what as its</p> <p>6 title?</p> <p>7 A. 510(k) Sterility Review Guidance. There's</p> <p>8 actually a guidance document that you can get. It's</p> <p>9 the same document.</p> <p>10 Q. All right. What is the significance, if</p> <p>11 any, of that document to your TVT-Secur opinions in</p> <p>12 the MDL?</p> <p>13 A. Well, the 1997 document says that the</p> <p>14 reviewer is not going to review the sterility</p> <p>15 information. They're going to leave that until a</p> <p>16 facility inspection. So it was kind of a change in</p> <p>17 policy because FDA actually had looked at sterility</p> <p>18 data up until '97. In '97 they stopped.</p> <p>19 Q. Why?</p> <p>20 A. You know, I don't know why they did. They</p> <p>21 stopped because I think they wanted to cut cost. It</p> <p>22 takes a lot for a reviewer, and it -- they wanted to</p> <p>23 speed up the process, and they decided that they</p> <p>24 would check sterility information when they did a</p> <p>25 good manufacturing practices quality systems</p>
<p style="text-align: right;">Page 39</p> <p>1 Q. -- the guidance?</p> <p>2 (Whereupon, Exhibit No. 13 was marked</p> <p>3 for identification.)</p> <p>4 BY MR. GAGE:</p> <p>5 Q. All right. Then the final exhibit is</p> <p>6 Exhibit No. 13. It's a single sheet of paper, at</p> <p>7 the top of which it says, "Microbiological Safety."</p> <p>8 Dr. Parisian, what is that document?</p> <p>9 A. This is the ETHISORB Dura Patch. I was</p> <p>10 looking at the -- there's some microscopic</p> <p>11 information about it.</p> <p>12 Q. What is the significance of that document,</p> <p>13 if any, to your TVT-Secur opinion?</p> <p>14 A. Well, TVT uses the -- that patch. That's</p> <p>15 what the arms are is the ETHISORB Dura Patch. So I</p> <p>16 was looking for documents about the Dura Patch.</p> <p>17 Q. Well, I should be perhaps more pointed.</p> <p>18 Is there anything specific in that document</p> <p>19 that impacts your opinion one way or the other about</p> <p>20 the safety or efficacy of the TVT-Secur?</p> <p>21 A. Not anything other than what I've written in</p> <p>22 my report, but I'm giving it to you to be complete.</p> <p>23 (Whereupon, Exhibit No. 14 was marked</p> <p>24 for identification.)</p> <p>25 ///</p>	<p style="text-align: right;">Page 41</p> <p>1 inspection.</p> <p>2 Q. Did you find this document on your own?</p> <p>3 A. I have it -- that one I don't think I did,</p> <p>4 but I have that document at home.</p> <p>5 Q. Where did you get this?</p> <p>6 A. It was in my papers here. I don't know</p> <p>7 where it came from, but there is a real guidance</p> <p>8 document that looks like a guidance document that</p> <p>9 goes with that, and I have it. But I don't know</p> <p>10 why, and that was just floating in these documents</p> <p>11 here.</p> <p>12 Q. You mentioned something about inspections?</p> <p>13 A. Yes, sir.</p> <p>14 Q. Does FDA have the power or the ability to</p> <p>15 conduct inspections of manufacturers of 510(k)</p> <p>16 cleared devices?</p> <p>17 A. Well, when? I mean, FDA has the authority</p> <p>18 to inspect manufacturing facilities. They're</p> <p>19 regulatory or required to do it every two years, but</p> <p>20 they're not making that. They're supposed to be</p> <p>21 inspecting.</p> <p>22 But are you talking about at the time of the</p> <p>23 510(k)?</p> <p>24 Q. No.</p> <p>25 Let's talk about Ethicon and the TVT-Secur.</p>



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<p style="text-align: right;">Page 42</p> <p>1 A. Okay.</p> <p>2 Q. During the time that the TVT-Secur was on</p> <p>3 the market, did FDA have the legal authority to</p> <p>4 conduct an inspection of Ethicon's manufacturing</p> <p>5 facilities and/or documents concerning TVT-Secur?</p> <p>6 MR. JONES: Objection.</p> <p>7 THE WITNESS: The FDA does have the</p> <p>8 legal authority, but it's at the -- it's at the</p> <p>9 pleasure of the company in terms of what they want</p> <p>10 to show the FDA.</p> <p>11 FDA doesn't just get cart blanche over,</p> <p>12 "We want to see all your documents." They can ask</p> <p>13 for them, and the manufacturer can say yes or no.</p> <p>14 But do they have the authority to</p> <p>15 inspect? Yes, the FDA does. Do they have the</p> <p>16 resources to inspect? Not much. That's where</p> <p>17 they're falling behind.</p> <p>18 BY MR. GAGE:</p> <p>19 Q. When they conduct an inspection, what do</p> <p>20 they inspect?</p> <p>21 A. Usually pick maybe one or two devices as</p> <p>22 kind of exemplary type of things that they look at,</p> <p>23 and they're looking for systemic error or some kind</p> <p>24 of an issue. And so they don't inspect everything.</p> <p>25 They don't have time or resources to inspect</p>	<p style="text-align: right;">Page 44</p> <p>1 Q. Do regulatory bodies outside of the United</p> <p>2 States have the authority to conduct inspections or</p> <p>3 audits of a medical device manufacturer, such as</p> <p>4 Ethicon, and a device like the TVT-Secur?</p> <p>5 MR. JONES: Objection.</p> <p>6 THE WITNESS: They have the authority.</p> <p>7 I mean, the thing is resources. Because now we're</p> <p>8 even using -- in the United States, we're using</p> <p>9 foreign inspectors to try to catch -- catch up on</p> <p>10 our inspecting of facilities. You know, they're</p> <p>11 trying to harmonize them and so they can inspect.</p> <p>12 But, you know, I don't -- I don't</p> <p>13 think -- and I didn't discuss any of the inspections</p> <p>14 in my report.</p> <p>15 BY MR. GAGE:</p> <p>16 Q. During the time period when TVT-Secur was on</p> <p>17 the market, if FDA conducted an inspection or an</p> <p>18 audit, could they ask to see any document the</p> <p>19 company may have with regard to TVT-Secur, or can</p> <p>20 they only ask for a subset of documents?</p> <p>21 MR. JONES: Objection.</p> <p>22 THE WITNESS: They can ask. The</p> <p>23 company doesn't have to provide them. Usually they</p> <p>24 will put it in their inspection report if the</p> <p>25 company refused, so the company is allowed to</p>
<p style="text-align: right;">Page 43</p> <p>1 everything. That's when they come to a facility</p> <p>2 inspection.</p> <p>3 Sometimes in the documents I saw for the FDA</p> <p>4 work committee, they actually were sending</p> <p>5 inspectors in to try to get information about the --</p> <p>6 so that's kind of a directed inspection where</p> <p>7 they'll have a district office person go in and get</p> <p>8 some documents that they're asking for.</p> <p>9 The FDA has fairly limited ability to</p> <p>10 inspect. They can, but they don't.</p> <p>11 Q. Just with respect to TVT-Secur and Ethicon,</p> <p>12 did FDA ever conduct any inspections?</p> <p>13 A. I don't know. In the document that I saw</p> <p>14 from the FDA in 2007, 2008, they were talking about</p> <p>15 going and doing an inspection to get information of</p> <p>16 all manufacturers, so I don't know.</p> <p>17 Q. Did any other regulatory body conduct any</p> <p>18 inspections or audits of Ethicon for its pelvic mesh</p> <p>19 devices while TVT-Secur was on the market?</p> <p>20 A. You mean in the United States?</p> <p>21 Q. In any country.</p> <p>22 A. I'm not aware of them inspecting. I know</p> <p>23 that they were having to deal with other countries</p> <p>24 outside the United States, but I'm not aware of</p> <p>25 anything specific.</p>	<p style="text-align: right;">Page 45</p> <p>1 refuse.</p> <p>2 And every inspection for a medical</p> <p>3 device company is announced, so it's not like the</p> <p>4 FDA surprises them. They know they're coming. They</p> <p>5 know what they're going to ask for. And it's -- and</p> <p>6 it's supposed to be at the convenience of the</p> <p>7 company.</p> <p>8 BY MR. GAGE:</p> <p>9 Q. Dr. Parisian, do you consider your TVT-Secur</p> <p>10 report to be complete?</p> <p>11 A. At this moment in time, I don't have</p> <p>12 anything else that I want to add to it.</p> <p>13 Q. All right. So you have no current plans to</p> <p>14 supplement the opinions. Is that correct?</p> <p>15 A. As far as I know, yes, sir.</p> <p>16 Q. Do you have any plans to do any additional</p> <p>17 work with regard to TVT-Secur?</p> <p>18 A. No, sir. I have not been requested to do</p> <p>19 anything else.</p> <p>20 Q. Is there any information that you're waiting</p> <p>21 on relating to TVT-Secur which might cause you to</p> <p>22 change or alter the opinions in your report?</p> <p>23 A. No.</p> <p>24 Q. Have you asked plaintiffs' counsel for any</p> <p>25 documents or other papers that you may need with</p>

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<p style="text-align: right;">Page 46</p> <p>1 regard to TVT-Secur?</p> <p>2 A. No.</p> <p>3 Q. All right. Dr. Parisian, going back to your</p> <p>4 reliance list, am I correct that Clark, Love gave</p> <p>5 you the notebook that's been attached as Exhibit 6?</p> <p>6 Correct?</p> <p>7 A. Yes, sir.</p> <p>8 Q. Did you get any additional documents from</p> <p>9 anyone other than the ones that we've already</p> <p>10 discussed and marked?</p> <p>11 A. No, sir.</p> <p>12 Q. So is it -- is it a true statement that your</p> <p>13 MDL report on TVT-Secur was based on the documents</p> <p>14 that we have marked already as exhibits with the</p> <p>15 understanding that you're going to go back and look</p> <p>16 to see if there were some additional documents or</p> <p>17 depositions that were not contained either in your</p> <p>18 reliance list or in the notebook marked Exhibit 6?</p> <p>19 A. Yes.</p> <p>20 MR. JONES: Objection.</p> <p>21 THE WITNESS: Yes, sir.</p> <p>22 MR. GAGE: What's the objection?</p> <p>23 MR. JONES: The exhibits to the</p> <p>24 deposition, I don't think you included that in the</p> <p>25 deposition. Her testimony, the multiple</p>	<p style="text-align: right;">Page 48</p> <p>1 for years. She's worked on mesh litigation outside</p> <p>2 of TVT-Secur. The reliance list and the materials I</p> <p>3 just referenced are limited to her TVT-Secur</p> <p>4 materials.</p> <p>5 That doesn't mean that materials she's</p> <p>6 reviewed for Prolift+M or, you know, other mesh</p> <p>7 litigation doesn't generally support her opinions.</p> <p>8 So that's the distinction for me.</p> <p>9 I don't want to get into a spot where</p> <p>10 you're trying to hammer down and box her into this</p> <p>11 one specific issue. Oh, wait, she talked for 30,</p> <p>12 you know, pages, or she reviewed this, you know,</p> <p>13 article. It just didn't appear on her TVT-Secur</p> <p>14 list because it was on another list, Prolift+M,</p> <p>15 or -- you know, we get into the issue of you go</p> <p>16 back -- years back to the medical school education.</p> <p>17 That's my issue, that she's reviewed stuff for --</p> <p>18 what? -- four, five years now -- three, four, five</p> <p>19 years on surgical mesh and transvaginal mesh</p> <p>20 specifically.</p> <p>21 And those obviously are going to impact</p> <p>22 her opinions generally. They might not specifically</p> <p>23 relate to TVT-Secur, but she's going to rely on that</p> <p>24 expertise that she's formed over the past four years</p> <p>25 working on mesh.</p>
<p style="text-align: right;">Page 47</p> <p>1 disclosures, we still haven't got to the bottom of</p> <p>2 the supplemental disclosure issue.</p> <p>3 I think he's made a reference that it</p> <p>4 wasn't actually filed or served.</p> <p>5 MR. GAGE: Oh, the supplemental?</p> <p>6 MR. JONES: I just want to make sure</p> <p>7 that the supplemental disclosure, her testimony, the</p> <p>8 exhibits that were included, the prior deposition of</p> <p>9 TVT-Secur, to me, it's just -- there's a broader</p> <p>10 universe than what you included in your question.</p> <p>11 MR. GAGE: That's good to know.</p> <p>12 BY MR. GAGE:</p> <p>13 Q. So if we include the documents that counsel</p> <p>14 just referenced, then, Dr. Parisian, is it correct</p> <p>15 to say that would be the entirety of the universe of</p> <p>16 the documents that you have reviewed and/or relied</p> <p>17 upon in preparing your MDL Secur opinion with the</p> <p>18 exception of the documents that you are going to go</p> <p>19 back and check and deposition exhibits?</p> <p>20 MR. JONES: And objection.</p> <p>21 Do you want me to explain the</p> <p>22 objection?</p> <p>23 MR. GAGE: Please do.</p> <p>24 MR. JONES: The objection is, the issue</p> <p>25 is for me, you know, she's worked on mesh litigation</p>	<p style="text-align: right;">Page 49</p> <p>1 MR. GAGE: Yeah, and I understand that.</p> <p>2 And I think my questions are much more directed</p> <p>3 toward learning what documents did you receive for</p> <p>4 the purpose of drafting a TVT-Secur report?</p> <p>5 MR. JONES: Okay. And then -- and then</p> <p>6 if you want to break it up even more to internal</p> <p>7 documents, then that makes it somewhat easier,</p> <p>8 because then, you know, if it's related to the</p> <p>9 Ethicon internal documents on TVT-Secur, then that,</p> <p>10 to me, breaks it up and makes it more specific.</p> <p>11 Again, she's reviewed an internal</p> <p>12 document that may not be specifically about</p> <p>13 TVT-Secur. But we were just going back and forth</p> <p>14 about PROLENE and what exactly does PROLENE mean.</p> <p>15 Well, it might not be on her TVT-Secur list, a</p> <p>16 document that speaks to PROLENE. But that's</p> <p>17 generally going to support her opinions in a</p> <p>18 TVT-Secur report if you're going to ask her about,</p> <p>19 well, what is PROLENE?</p> <p>20 BY MR. GAGE:</p> <p>21 Q. Well, let me ask you this: She's got two</p> <p>22 reliance lists in the -- in Ethicon cases, either</p> <p>23 the Prolift+M or the TVT-Secur reliance list;</p> <p>24 correct?</p> <p>25 A. Yes, sir.</p>



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<p style="text-align: right;">Page 50</p> <p>1 Q. And we covered exhaustively today what you 2 have and have not reviewed with regard to Prolift+M; 3 correct? 4 A. We covered what I reviewed, yes. 5 Q. Right. 6 With regard to TVT-Secur and your federal 7 opinion, I assume you reviewed some, if not all, of 8 the documents regarding Prolift+M while you were 9 working on your TVT-Secur opinion. 10 Is that a correct statement? 11 A. Well, they're all cumulative. I think 12 that's what he's trying to say. 13 Q. And I'm not suggesting they're not 14 cumulative. I'm just trying to get an understanding 15 of, so, I've got a basket of documents that were -- 16 that were -- they fall into two categories. For 17 Prolift+M, they're documents that were either sent 18 to you or you got them yourself? 19 A. Yes. 20 Q. For TVT-Secur, there's a basket of documents 21 that were either sent to you or you got yourself? 22 A. Right. 23 Q. You don't have any other reports for any 24 other Prolift or any other Ethicon devices? 25 A. That's correct.</p>	<p style="text-align: right;">Page 52</p> <p>1 mesh. So, I mean, I know about poly and we use -- 2 Q. And I'm not trying to limit your knowledge 3 to just the documents you received. I'm trying to 4 drive at whether there is a universe, a group, a 5 list, a cache, a collection of documents -- 6 A. Right. 7 Q. -- that you have reviewed for your Ethicon 8 work, be it Prolift+M or TVT-Secur, beyond the 9 documents that we have marked as exhibits either to 10 the Prolift+M deposition or to the TVT-Secur 11 deposition. 12 That's really where I'm just trying to get 13 at. 14 MR. JONES: Understanding she's worked 15 on additional mesh litigation related to 16 transvaginal mesh products. 17 MR. GAGE: Yes. 18 BY MR. GAGE: 19 Q. All right. So I'll ask this question: Have 20 you reviewed Ethicon documents for other mesh 21 litigation that does not appear on your reliance 22 list for Prolift+M or TVT-Secur? 23 MR. JONES: Ethicon internal corporate 24 documents? 25 MR. GAGE: Yes.</p>
<p style="text-align: right;">Page 51</p> <p>1 MR. JONES: And just object. 2 The issue for me, you're saying 3 documents. In your documents, you're including 4 literature, regulations, internal documents, 5 records, whatever. 6 I mean, you're not meaning internal 7 documents, internal Ethicon documents? 8 MR. GAGE: No. I'm being broader than 9 that because I think no matter how broadly you 10 categorize them, they still fall into one of those 11 two buckets. I either got them alone or I got them 12 from somebody else. 13 THE WITNESS: Or I know about the 14 issues anyway. 15 MR. JONES: Or she already knew it. 16 MR. GAGE: Right. 17 BY MR. GAGE: 18 Q. But if it's a document, you can't -- you got 19 to specifically have it in your hands. You either 20 had to go get it or somebody had to give it to you. 21 A. Right. 22 Q. It has to be one of those two things. 23 A. But like we were talking about 24 polypropylene, and I know polypropylene from lots of 25 other issues that has nothing to do with vaginal</p>	<p style="text-align: right;">Page 53</p> <p>1 THE WITNESS: I looked at Ethicon 2 documents. I don't know if they're internal. Like 3 TVT, I looked at -- somewhere along the line, I've 4 seen the 510(k) for TVT and some of the interaction 5 back and forth between the FDA. And I don't think 6 it would have been in an Ethicon litigation, but 7 there were documents that other people had. 8 So I've seen other Ethicon documents, 9 TVT-O, TVT, so -- but I'm not involved in those 10 cases at this point in time. And so, you know -- 11 but I have seen those documents, but I haven't seen 12 the Ethicon version of the -- I've seen -- 13 Because other manufacturers would go 14 get Ethicon documents, and they're usually FYI 15 documents; right? They've been redacted. So I have 16 seen Ethicon documents but not necessarily internal 17 documents. 18 BY MR. GAGE: 19 Q. Okay. So now let me -- let me limit your -- 20 let me change the question. 21 A. Okay. 22 Q. Let's talk about only the documents that you 23 have received from lawyers who were making claims 24 against Ethicon. I don't want to talk at all about 25 documents that maybe the AMS lawyers gave you. I</p>

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<p style="text-align: right;">Page 54</p> <p>1 want to talk about the documents that the lawyers 2 representing the plaintiffs in the Ethicon 3 litigation have given you. 4 Do you have any group or list of documents 5 for either Prolift+M or TVT-Secur other than the 6 ones that you have shared with us today in either 7 the Prolift+M deposition or the TVT-Secur 8 deposition? 9 A. No. Other than I'm going to go look at the 10 depos and see what I have. 11 Q. That's what I needed to -- 12 A. So I've given you my file. 13 Q. Okay. Now, with regard to the medical 14 literature pertinent to your opinions -- strike 15 that. 16 Regarding the medical opinions regarding 17 TVT-Secur, is it correct to say that the literature 18 that you have reviewed with regard to TVT-Secur is 19 either found in the notebook that's attached as 20 Exhibit 6 or in your reliance list that we've 21 marked, or is otherwise already marked as one of the 22 exhibits in -- in -- to this deposition? 23 A. I'm looking to see if the -- 24 MR. JONES: Objection. 25 THE WITNESS: -- Cochrane report is in</p>	<p style="text-align: right;">Page 56</p> <p>1 the one I have that, Exhibit 6 or 7 -- 2 Q. Yes. 3 A. -- they were talking about the Cochrane 4 report. They didn't have the whole Cochrane report 5 in it. And so that -- I don't see that it's listed 6 on my list, and so that would be something else 7 that's in there in terms of TVT-Secur. 8 Q. Do you have a list of documents that fall 9 into that category? 10 And just so that we're clear, the category 11 is -- 12 MR. JONES: What is the category? 13 MR. GAGE: The category is, "The list 14 of documents that I'm relying upon that form the 15 basis for my TVT-Secur opinions which do not appear 16 in my reliance list or in Exhibit 6." 17 MR. JONES: And what's the scope of 18 that? 19 MR. GAGE: Well, she was able to 20 specifically recall very acutely the -- the -- 21 THE WITNESS: Cochrane review? 22 BY MR. GAGE: 23 Q. -- the Cochrane review, and so I would ask 24 you, do you have a list or a -- either a written 25 list or a mental list of, "Here are 8 or 10 or 15 or</p>
<p style="text-align: right;">Page 55</p> <p>1 here because the Cochrane report I reviewed for 2 something, and so I've reviewed the Cochrane report 3 even before I got involved in this, and so in terms 4 of TVT-Secur, that's in there. 5 BY MR. GAGE: 6 Q. All right. So let me ask you this: When -- 7 when -- is there a list of documents -- see, I 8 understand -- for example, I think what you're 9 saying is like with Cochrane review, you were given 10 that document -- or were you given that document, or 11 did you go find it on your own? 12 A. I went and found it, but it wasn't for 13 TVT-Secur. It was looking at mini slings, so I was 14 looking at mini slings, and the TVT-Secur is the one 15 that's in the Cochrane report. There's a lot of 16 discussion about it. 17 Q. Okay. So that document, the Cochrane 18 review, is not going to be in Exhibit 6? 19 A. No, but I had seen it before. 20 Q. I understand. 21 It's not in Exhibit 6; right? 22 A. I don't -- I don't know. It may be. That's 23 why I was looking in this report, because I mean, 24 that is relevant to TVT-Secur, and then the FDA 25 document when they were talking about it yesterday,</p>	<p style="text-align: right;">Page 57</p> <p>1 20 or 100 documents that I know are pertinent to 2 TVT-Secur but which don't appear on my reliance list 3 or in this notebook"? 4 A. That's the only one I can really think of 5 because that's a biggie, but I had read that with 6 nothing to do with TVT-Secur. I was looking at 7 single incision slings, and so that was something 8 that -- that TVT-Secur is in that. 9 Q. Did you do a PubMed search for TVT-Secur? 10 A. I don't think I did. 11 Q. Did you do a functional equivalent of a 12 PubMed research? I understand you can do it by 13 using PubMed or some other service. 14 Did you do either a PubMed or some other 15 functionally equivalent medical literature search 16 for TVT-Secur? 17 A. I don't recall that I did. I don't recall 18 that I -- I ever did because TVT -- I mean, TVT has 19 been involved in so many other cases, I didn't do a 20 search for TVT-Secur. 21 Q. And I take it you have already produced what 22 you would consider to be your complete file to us -- 23 to me today? 24 A. Yes, sir, other than the depos that I didn't 25 print out.</p>

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<p style="text-align: right;">Page 58</p> <p>1 Q. Have you ever spoken with anyone who you 2 understand to be an expert in the mesh litigation 3 with regard to your TVT-Secur opinions? 4 A. No. 5 Q. With regard to your documents and invoices 6 reflecting compensation regarding TVT-Secur, where 7 is that? 8 A. I didn't bring them. I didn't see the depo 9 notice, so I didn't bring them. 10 Q. Shame on you. 11 A. I know. 12 Q. I hereby mark that witness's answer in the 13 event you guys complain one bit if one of my experts 14 doesn't bring it. So noted says the plaintiffs' 15 lawyers. 16 A. Well, normally when I see the notice, I pull 17 everything out. I didn't see a notice, so I didn't 18 do it. 19 Q. Can we -- can I ask you to provide that 20 documentation to Nate, and, Nate, will you agree to 21 provide that? 22 MR. JONES: Absolutely. It's coming. 23 And I'll look for the post-it note binder at the 24 next deposition from the defense experts -- 25 MR. GAGE: Thank you.</p>	<p style="text-align: right;">Page 60</p> <p>1 that. Not knowing really what logistically is 2 required, what I'm getting myself into. Generally, 3 yes. 4 MR. GAGE: If you want to later, you 5 know, object or call me and say, I now have a reason 6 for it, I'll understand. I'm not going to go nuts 7 on you, but I do think we're entitled to it. And I 8 do think it would be very helpful if we attach that 9 document, even though we haven't seen it, as the 10 next exhibit. What Exhibit No. would that be, Madam 11 Court Reporter? 12 The parties have agreed, subject to 13 Nate's perhaps needing to reconsider, as Exhibit 15 14 the document that Dr. Parisian will provide to Nate 15 that reflects her compensation for the work that 16 she's done with regard to TVT-Secur in the MDL. 17 (Whereupon, Exhibit No. 15 was later 18 marked for identification.) 19 BY MR. GAGE: 20 Q. Dr. Parisian, do you have any recollection 21 of how much time you would have spent on the 22 TVT-Secur work in the MDL? 23 A. No, I don't. I don't, because I know that 24 you had the bill from Garcia. I produced the bill 25 for that, and then the depo, and then I don't know</p>
<p style="text-align: right;">Page 59</p> <p>1 MR. JONES: -- which I know will not be 2 produced. 3 MR. GAGE: Oh, of course you know it 4 will. 5 I'll tell you what. What we probably 6 ought to do, if we can agree to do this, can we go 7 ahead and agree -- and, Madam Court Reporter, you 8 might say you don't want to do this, but let's see 9 if y'all will agree to it. 10 Can we agree to mark that document that 11 reflects her compensation on her MDL TVT-Secur work 12 as the next exhibit to this deposition, so that when 13 you produce it to me -- 14 MR. JONES: It will be part of the 15 record? 16 MR. GAGE: -- can you go ahead and send 17 it to this court reporter so she can make it part of 18 the record so that it carries forward in perpetuity 19 with the depo, and you and I don't have to keep 20 trying to find it later on? 21 MR. JONES: I think -- I think that's 22 something I will try my best to do. Absolutely. 23 MR. GAGE: All right. And let's make 24 sure -- 25 MR. JONES: I don't see a problem with</p>	<p style="text-align: right;">Page 61</p> <p>1 what -- because we're only talking about the report, 2 so I don't know what that was. 3 Q. What is your hourly rate? 4 A. \$400 an hour for in my office. \$600 an hour 5 for this today. 6 Q. Deposition? 7 A. Yes, sir. And testimony in court. 8 Q. Is \$600 a day? 9 A. No. An hour. 10 Q. I'm sorry. \$600 an hour for trial 11 testimony? 12 A. Yes, sir. 13 Q. All right. Do you know how much time you 14 spent reviewing documents for your TVT-Secur work as 15 opposed to actually writing your TVT-Secur opinion? 16 A. No. Because, see, that's a protracted one 17 in that I've done disclosure, and there was time for 18 that, so you should have had the bill from the 19 disclosure, when we came out with, you know, my 20 review time, and so then when it came to writing the 21 report, it really -- I had already made opinions and 22 stuff, so it didn't take that long to write the 23 report for the MDL. 24 Q. When you -- you were obviously asked 25 sometime in 2015 to write the report for the MDL;</p>

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<p style="text-align: right;">Page 62</p> <p>1 right?</p> <p>2 A. Right.</p> <p>3 Q. As I understand it, because of your prior</p> <p>4 work in Garcia and because the documents were</p> <p>5 essentially the same, is that a correct statement</p> <p>6 that the documents you reviewed and relied upon in</p> <p>7 Garcia are essentially the same?</p> <p>8 A. Yes.</p> <p>9 Q. And I used the word "essentially." I'm not</p> <p>10 trying to trap you and say identically --</p> <p>11 A. Right.</p> <p>12 Q. -- but they're essentially the same --</p> <p>13 A. Right.</p> <p>14 Q. -- as between Garcia and the MDL report?</p> <p>15 A. Right.</p> <p>16 Q. Have you published any of the opinions</p> <p>17 you're offering about TVT-Secur?</p> <p>18 A. No.</p> <p>19 Q. Have you spoken with any scientist,</p> <p>20 engineer, or medical doctor regarding your Secur</p> <p>21 opinions?</p> <p>22 A. No.</p> <p>23 Q. Is it correct to say that you developed your</p> <p>24 TVT-Secur opinions specifically for litigation and</p> <p>25 not for a research project or formal study?</p>	<p style="text-align: right;">Page 64</p> <p>1 But it's not causation, per se. It's just</p> <p>2 limiting the world to the time that's relevant to</p> <p>3 that patient.</p> <p>4 Q. Right.</p> <p>5 And so, for example, you don't review a</p> <p>6 patient -- a particular patient's medical records</p> <p>7 and then render a medical opinion as to the cause of</p> <p>8 that particular plaintiff's alleged injuries, for</p> <p>9 example?</p> <p>10 A. Yes. I try to keep the amount of medical</p> <p>11 records review low. I will pay attention to what</p> <p>12 the physician says as to what he knew and what the</p> <p>13 labeling should have been because that feeds into</p> <p>14 the actions that the company could have taken to</p> <p>15 notify that doctor, so that's part of my pattern</p> <p>16 too.</p> <p>17 MR. GAGE: And, Nate, can we have the</p> <p>18 same stipulation from counsel as you gave us in the</p> <p>19 Prolift+M deposition, that you do not intend to put</p> <p>20 up Dr. Parisian as a case-specific expert apart from</p> <p>21 the discussion that we just had with her?</p> <p>22 MR. JONES: Yeah, yes.</p> <p>23 BY MR. GAGE:</p> <p>24 Q. Dr. Parisian, am I correct you do not have</p> <p>25 any manufacturing defect opinions with regard to</p>
<p style="text-align: right;">Page 63</p> <p>1 A. Yes.</p> <p>2 Q. And as we discussed at your Prolift+M</p> <p>3 deposition, you don't have case-specific opinions</p> <p>4 that you intend to render with regard to any</p> <p>5 particular TVT-Secur patient; correct?</p> <p>6 A. I'm not their medical causation person.</p> <p>7 Q. And I think you testified in your Prolift+M</p> <p>8 deposition that the extent of your case-specific</p> <p>9 opinions would be a review of the information</p> <p>10 necessary for you to determine issues, such as the</p> <p>11 date on which a particular patient may have been</p> <p>12 implanted, in order to determine what perhaps might</p> <p>13 be the applicable patient brochure and/or where to</p> <p>14 place that particular plaintiff's implant date in</p> <p>15 against the backdrop of some regulatory timeline.</p> <p>16 Is that correct?</p> <p>17 A. In terms of the timeline Ethicon was dealing</p> <p>18 with in terms of what they knew, when, yeah. When</p> <p>19 you go to court -- the reports are written general,</p> <p>20 and so when you go to court, you have to have a more</p> <p>21 honed in time period so that it's relevant to the</p> <p>22 patient.</p> <p>23 And so I usually use their time frame in</p> <p>24 order to kind of hone in my regulatory opinions and</p> <p>25 my opinions of the physician as to what's going on.</p>	<p style="text-align: right;">Page 65</p> <p>1 TVT-Secur?</p> <p>2 A. Naming individual lot to lot, no, I don't</p> <p>3 have any. Obviously, I talk about design in terms</p> <p>4 of adequacy of design and follow-up and complaint</p> <p>5 handling, but a specific lot defect, no, because I</p> <p>6 don't even know who the patients are. How can I</p> <p>7 have --</p> <p>8 Q. But once you find out who the specific</p> <p>9 patient is, it's not your -- it's not your role to</p> <p>10 look at a specific lot and then make a medical or</p> <p>11 render a medical causation opinion. Is that</p> <p>12 correct?</p> <p>13 A. I've been asked to do that sometimes, but</p> <p>14 I'm not -- I'm not planning on doing it because</p> <p>15 oftentimes we don't have the lot information on</p> <p>16 these things, and I need to have the -- I need to</p> <p>17 have manufacturing records.</p> <p>18 If I get the manufacturing records, I may</p> <p>19 look at it. Sometimes it pops up, but I don't know</p> <p>20 of one right now.</p> <p>21 Q. To date, have you reviewed any TVT-Secur</p> <p>22 manufacturing records?</p> <p>23 A. No.</p> <p>24 Q. And you're not here as a representative of</p> <p>25 FDA; correct?</p>

17 (Pages 62 to 65)

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<p style="text-align: right;">Page 66</p> <p>1 A. That is correct.</p> <p>2 Q. You're not here speaking on behalf of the</p> <p>3 FDA; correct?</p> <p>4 A. That is correct.</p> <p>5 Q. FDA has not reviewed or endorsed any of your</p> <p>6 opinions in this case?</p> <p>7 A. That is correct.</p> <p>8 Q. Have you ever spoken with anyone from FDA</p> <p>9 regarding your Secur opinions?</p> <p>10 A. No.</p> <p>11 Q. Have you ever called or written to FDA about</p> <p>12 any of your Secur opinions?</p> <p>13 A. No.</p> <p>14 Q. While you were at the FDA, did you ever have</p> <p>15 any involvement with TVT-Secur?</p> <p>16 A. No.</p> <p>17 Q. Any involvement with any of the predicates</p> <p>18 to TVT-Secur?</p> <p>19 A. I don't think so. I mean, you're -- I don't</p> <p>20 think so. I mean, I was in urological devices, but</p> <p>21 I didn't see anything there. And the surgical mesh,</p> <p>22 I was involved with some surgical mesh, but nothing</p> <p>23 specific to the urological use. I came after -- I</p> <p>24 left before ProtoGen and before TVT.</p> <p>25 Q. Dr. Parisian, I asked you this morning in</p>	<p style="text-align: right;">Page 68</p> <p>1 but I wouldn't. I don't think that I would be the</p> <p>2 right person to counsel somebody about that.</p> <p>3 Q. Why not?</p> <p>4 A. I wouldn't counsel a patient about treatment</p> <p>5 of their urological problems. I mean, there are</p> <p>6 certain things I do know. I mean, patients will ask</p> <p>7 me, "What have you seen in terms of litigation and</p> <p>8 stuff?" I wouldn't do that.</p> <p>9 That's -- that's a patient and a physician</p> <p>10 that talk about that.</p> <p>11 Q. If someone came to you wanting to counsel</p> <p>12 with you about treatment options for SUI, what would</p> <p>13 you tell them?</p> <p>14 A. I would tell them that -- what would I tell</p> <p>15 them? I would tell them Kegel exercises, what I</p> <p>16 know, and pumpkin seed. You know, other things that</p> <p>17 are noninvasive, and maybe push them on to a</p> <p>18 urogynecologist, something like that. That's not</p> <p>19 mine.</p> <p>20 I mean, everybody has to have their own --</p> <p>21 I'm not a -- I'm not a practicing physician right</p> <p>22 now in terms of counseling patients what to do.</p> <p>23 Q. Have you ever seen a TVT-Secur implanted in</p> <p>24 the body?</p> <p>25 A. No.</p>
<p style="text-align: right;">Page 67</p> <p>1 your Prolift+M deposition a number of questions</p> <p>2 about board certification, staff privileges,</p> <p>3 credentials at hospitals and studies that you may or</p> <p>4 may not have done with regard to surgical mesh.</p> <p>5 Is it fair to say that the answers you gave</p> <p>6 in the deposition this morning would be translatable</p> <p>7 to this deposition such that I do not have to re-ask</p> <p>8 those?</p> <p>9 A. Yes, sir. I have not changed in that period</p> <p>10 of time.</p> <p>11 Q. Is it correct that you never did any kind of</p> <p>12 mechanical testing of the mesh in TVT-Secur?</p> <p>13 A. Yes.</p> <p>14 Q. You did not do any type of testing or</p> <p>15 measurements of the mesh in TVT-Secur?</p> <p>16 A. Correct.</p> <p>17 Q. And that's not something you would do in</p> <p>18 your normal practice. Is that correct?</p> <p>19 A. Correct. I would normally look at the data</p> <p>20 and not test it.</p> <p>21 Q. Do you believe you have the requisite</p> <p>22 education, training, and experience to counsel a</p> <p>23 patient about treatment options for stress urinary</p> <p>24 incontinence?</p> <p>25 A. You know, I probably could as a physician,</p>	<p style="text-align: right;">Page 69</p> <p>1 Q. And by that, I mean have you ever watched a</p> <p>2 TVT-Secur being implanted in someone?</p> <p>3 A. No.</p> <p>4 Q. Have you ever watched a video of a TVT-Secur</p> <p>5 procedure?</p> <p>6 A. No.</p> <p>7 Q. Have you ever held a TVT-Secur in your hand?</p> <p>8 A. No.</p> <p>9 Q. Have you ever been in the same room as a</p> <p>10 TVT-Secur device?</p> <p>11 MR. JONES: Sorry. When you get to a</p> <p>12 stopping point, break --</p> <p>13 THE WITNESS: No.</p> <p>14 MR. GAGE: Let's take a stopping point.</p> <p>15 MR. JONES: Thanks.</p> <p>16 (Recess taken.)</p> <p>17 BY MR. GAGE:</p> <p>18 Q. All right. Dr. Parisian, do you agree that</p> <p>19 you do not have the requisite education, training,</p> <p>20 and experience to implant a TVT-Secur?</p> <p>21 A. Yeah.</p> <p>22 Q. And do you agree that you have not had the</p> <p>23 requisite education, training, and experience to</p> <p>24 counsel a patient about the risks and benefits of</p> <p>25 TVT-Secur?</p>



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<p style="text-align: right;">Page 70</p> <p>1 A. Yeah. I wouldn't -- I wouldn't do that.  2 That was not what I would do.  3 Q. Would you agree that there are patients who  4 have had TVT-Secur who have had no complications?  5 A. I don't know.  6 Q. Would you agree that there are patients who  7 have had a good experience with TVT-Secur?  8 A. I -- I don't know. I don't know what the  9 patient experience is.  10 Q. Would you agree that there are women who  11 have had a TVT-Secur placed where it has been a safe  12 and effective device for them?  13 MR. JONES: Objection.  14 THE WITNESS: It's the same answer. I  15 don't know.  16 BY MR. GAGE:  17 Q. Do you know if there are pelvic floor  18 surgeons in the United States who believe the  19 TVT-Secur was safe and effective?  20 A. I don't know.  21 Q. If there were such doctors, would you  22 disagree with them on that point?  23 A. Since I'm not implanting, I would let them  24 talk about it, but I'm sure there's other people  25 that would talk about the other side too, so I don't</p>	<p style="text-align: right;">Page 72</p> <p>1 A. No.  2 Q. Did that deposition inform your MDL opinion  3 in any way?  4 A. It fed into it. I don't reference it at all  5 in terms of that, but you asked me if I read a  6 deposition, yes, I read one.  7 Q. When you say it fed -- the reading of the  8 deposition fed into your MDL report, do you mean --  9 was there anything specific or in particular about  10 that deposition that caused you to change or caused  11 you to write any one of your MDL opinions in a  12 specific way, or do you just mean to say, hey, it's  13 part of the knowledge base that I had at the time  14 when I sat down to write the TVT-Secur report?  15 A. It's part of the knowledge base.  16 Q. Did you review any professional education  17 materials from Ethicon with regard to TVT-Secur?  18 A. I don't believe I did. I'm trying to  19 remember if I put in my report whether I referenced  20 any marketing.  21 You have a list of -- in my report, you  22 would have the documents that I've reviewed in terms  23 of the marketing of the company.  24 Q. Would it be fair to say that -- well, strike  25 that.</p>
<p style="text-align: right;">Page 71</p> <p>1 know.  2 Q. Have you written a draft IFU or a patient  3 brochure for TVT-Secur that is adequate in your  4 opinion?  5 A. No, I have not written a draft.  6 Q. Do you have any list or document or  7 PowerPoint slides or anything like that that would  8 purport to be a listing of words that need to be  9 either specifically added to the TVT IFU --  10 TVT-Secur IFU patient brochure or need to be taken  11 out of either the TVT-Secur IFU or patient brochure  12 in order to make them adequate?  13 A. No, I don't have a list.  14 Q. Have you ever spoken with a doctor who has  15 implanted a TVT-Secur?  16 A. No.  17 Q. Have you ever spoken to any pelvic floor  18 surgeon about the TVT-Secur IFU?  19 A. No.  20 Q. Have you read the depositions of any doctors  21 who have implanted TVT-Secur?  22 A. With Ms. Garcia I did. I forget who her  23 doctor was, but there were depositions from the  24 doctor.  25 Q. Any others beyond that?</p>	<p style="text-align: right;">Page 73</p> <p>1 And, Doctor, I want to ask you a question.  2 Do you draw any distinction between Ethicon  3 sponsored professional education and Ethicon  4 marketing?  5 A. They can overlap because sometimes marketing  6 will be in charge of the professional education, and  7 so they can overlap.  8 Q. What is your understanding of what the  9 professional education training for TVT-Secur  10 entailed?  11 A. Well, they would identify a physician that  12 would be like usually a key opinion leader or  13 trainer, someone that knows the product, and then  14 they would usually have a class full of doctors who  15 want to learn about it. And they would probably use  16 cadavers, and they would oftentimes do pigs or some  17 other animal, and they would teach them how to do  18 the technique.  19 Q. Is that a good thing?  20 A. Is that a good thing? It's what is done in  21 terms of the procedure. That's not a bad thing.  22 The thing is that the design of the product  23 actually had some flaws to begin with, and you want  24 to design a product that would behave the way it's  25 supposed to. And this one had some major problems</p>



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<p style="text-align: right;">Page 74</p> <p>1 in terms of the design.</p> <p>2 Q. Are you critical of the Ethicon-sponsored</p> <p>3 professional education program for TVT-Secur?</p> <p>4 A. Not in the program. The issue is that the</p> <p>5 physicians weren't really learning about the</p> <p>6 potential risks and how difficult it was to do the</p> <p>7 procedure. So it's more with the contents.</p> <p>8 But to have a program, no, I'm not critical</p> <p>9 of their having a program.</p> <p>10 Q. Do you recall what documents you reviewed,</p> <p>11 if any, to determine what training and what risks</p> <p>12 were covered in the Ethicon-sponsored TVT-Secur</p> <p>13 professional education program?</p> <p>14 A. I have -- I looked at various company</p> <p>15 documents. I didn't look at a single course. I</p> <p>16 looked at -- and I think if you go to Opinion 7</p> <p>17 where I talk about the commercial use of the device,</p> <p>18 those are the documents that I looked at in there.</p> <p>19 And some of it would be company documents,</p> <p>20 the cookbooks, the tips and tricks, and -- but not</p> <p>21 necessarily a coursebook. Okay? So it would be</p> <p>22 under the Section B, and it would go 1 through 10.</p> <p>23 Q. Do you have a recollection of looking at any</p> <p>24 specific documents that were generated as a result</p> <p>25 of the Ethicon-sponsored professional education for</p>	<p style="text-align: right;">Page 76</p> <p>1 And, yes, if you took it together as all</p> <p>2 labeling, and you took the sales reps as all</p> <p>3 labeling, but they had been trained to teach this,</p> <p>4 then, yes, you could get away with that, in that</p> <p>5 their information, but it has to be accurate. It</p> <p>6 has to be fair and balanced in terms of the risk</p> <p>7 potential.</p> <p>8 Q. Did you -- I'm sorry.</p> <p>9 A. No, go ahead.</p> <p>10 Q. Did you undertake to do a comprehensive</p> <p>11 analysis of the TVT-Secur IFU, the TVT-Secur</p> <p>12 Ethicon-sponsored Prof. Ed, and the TVT-Secur</p> <p>13 patient brochure and other potential documents in</p> <p>14 order to come up with like an exhaustive list of</p> <p>15 every risk that the company warned about with regard</p> <p>16 to Secur?</p> <p>17 MR. JONES: Objection.</p> <p>18 THE WITNESS: I looked at the company</p> <p>19 documents. The company documents, you're talking</p> <p>20 about different risks that I didn't see reflected in</p> <p>21 the IFU or the training information or the patient</p> <p>22 brochure, so the company documents actually are the</p> <p>23 primary.</p> <p>24 And the information that you should see</p> <p>25 being given to the physician in some way should be</p>
<p style="text-align: right;">Page 75</p> <p>1 TVT-Secur?</p> <p>2 A. Not the coursework. That's why I say I was</p> <p>3 looking at things where they're internally talking</p> <p>4 about what they're going to put in the course.</p> <p>5 That's primarily what's there.</p> <p>6 Q. If those documents existed, would you want</p> <p>7 to see them?</p> <p>8 A. I don't know if I would be the person who</p> <p>9 would see them. It seems like it would be more of a</p> <p>10 surgeon that would see them in terms of who's done</p> <p>11 the procedure.</p> <p>12 I would look at them in terms of the way I</p> <p>13 was -- in terms of FDA's training in looking at</p> <p>14 labeling, but I think it would really be a surgeon</p> <p>15 that would probably be addressing what the contents</p> <p>16 are.</p> <p>17 Q. Dr. Parisian, let me ask you this: If</p> <p>18 Ethicon did not specifically disclose a risk of the</p> <p>19 TVT-Secur in the IFU but specifically disclosed the</p> <p>20 risk of -- that risk of TVT-Secur in another form,</p> <p>21 would that impact at all your opinions?</p> <p>22 A. Well, I mean, you may not have every --</p> <p>23 you're saying they may not have had everything in</p> <p>24 the IFU. They may have had some in the training</p> <p>25 materials.</p>	<p style="text-align: right;">Page 77</p> <p>1 coming from the information that the company has.</p> <p>2 And that's why my report is broken down talking</p> <p>3 about what the company knew internally, as opposed</p> <p>4 to the labeling and the training materials.</p> <p>5 BY MR. GAGE:</p> <p>6 Q. Did you look at any Ethicon-sponsored peer</p> <p>7 reviewed published medical literature to see whether</p> <p>8 that was a source of additional risk information for</p> <p>9 TVT-Secur?</p> <p>10 A. I did see some TVT-Secur in it. The problem</p> <p>11 with it is that it didn't tend to have a fair</p> <p>12 balance in terms of the risk.</p> <p>13 I mean, the FDA, when they went and they did</p> <p>14 a literature search, said that the information about</p> <p>15 transvaginal mesh wasn't adequate, that there hadn't</p> <p>16 been studies that had been done long enough with the</p> <p>17 success value criteria.</p> <p>18 Admittedly, those were for SUI and POP, not</p> <p>19 single incision. But the literature that I saw was</p> <p>20 similar, in that the TVT-Secur didn't have long</p> <p>21 enough follow-up, didn't have good valid end points.</p> <p>22 So there are complications -- problems with the</p> <p>23 literature that I did see.</p> <p>24 Q. Okay. Did you attempt, for example -- well,</p> <p>25 strike that.</p>

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<p style="text-align: right;">Page 78</p> <p>1 Did you look at the TVT-Secur published 2 medical literature in order to do a comparison 3 between the risks that were disclosed in that 4 literature versus the risks disclosed in either the 5 IFU or the brochure? 6 A. No. Because I'm looking at the internal 7 documents, which actually had more information about 8 risks than I saw in the IFU or the patient brochure. 9 Patient brochure has almost no risk 10 information. So, you know, you really need to look 11 at what the company is saying. The known, knowable 12 information, as opposed to the information that's 13 being provided. 14 (Whereupon, Exhibit No. 16 was marked 15 for identification.) 16 BY MR. GAGE: 17 Q. Doctor, I'm handing you a document marked 18 Parisian Exhibit No. 16. 19 Have you ever seen that document before? 20 A. I don't know. All these ladies start 21 looking alike in terms of these. I think I may 22 have. 23 When was this one published? 2008. 24 Q. Now, just to be clear, Dr. Parisian, did you 25 get that 2008 date from the -- kind of the trademark</p>	<p style="text-align: right;">Page 80</p> <p>1 BY MR. GAGE: 2 Q. Well, let me ask a question. 3 A. Patient brochures. 4 MR. GAGE: Nate, this is probably a 5 good discussion for you and me to have. 6 Have -- has counsel for plaintiff done 7 a comparison between her TVT-Secur expert report and 8 her reliance list to make sure those two match up, 9 or should I treat them as to -- 10 MR. JONES: What do you mean "match 11 up"? 12 MR. GAGE: That she may cite to 13 documents in her report that don't appear on the 14 reliance list? 15 MR. JONES: Have I gone through that? 16 MR. GAGE: Yes. 17 MR. JONES: No. That's your job. 18 THE WITNESS: This -- this is -- 19 MR. JONES: Unless you want to do that 20 for us on -- 21 THE WITNESS: This is in my report, 22 this document. 23 MR. GAGE: This exact document? 24 THE WITNESS: Yeah. 25 MR. JONES: So here's the deal.</p>
<p style="text-align: right;">Page 79</p> <p>1 on the very last page of this document? 2 A. Yes, sir. 3 Q. Okay. 4 A. Is that not correct? 5 Q. I don't know. I just wanted to know -- 6 MR. AYLSTOCK: Excellent question. 7 BY MR. GAGE: 8 Q. You said -- you threw out the date 2008. I 9 just didn't know where you got it from, and then I 10 just wanted to confirm, is that where you're getting 11 the date from? 12 A. That's where I'm getting the date from. 13 Q. Okay. 14 A. Look, the same people are in this one. 15 Q. Would it be -- would it be correct to say 16 that in order to answer the question whether you 17 have reviewed this specific document before you 18 wrote your TVT-Secur MDL report, I would need to 19 look at either the folder of documents we've marked 20 as an exhibit or your reliance list? 21 MR. JONES: Or you can just look at her 22 report. That discusses these items. 23 THE WITNESS: Yeah, because I'm looking 24 to see, because it's on page 99. What did I talk 25 about?</p>	<p style="text-align: right;">Page 81</p> <p>1 Earlier this morning when you were going back and 2 forth about the reliance list, things that you were 3 saying, hey -- and I objected, and I said, hey, I 4 don't think that's accurate. 5 They're listed in her report and so, 6 one, you know, she talks about them specifically in 7 her report, and then you're going to the reliance 8 list. I'm sure you had someone look at, run it -- 9 or on a computer look at, well, that ETH.MESH number 10 isn't on here. Well, maybe that ETH.MESH number is 11 listed in her report. 12 That is the same brochure listed under 13 a ETH.MESH in the reliance list. I don't know. I 14 haven't gone through and done that. 15 But I know that the brochure and IFUs 16 are discussed in her report, and I think 17 specifically -- I actually don't think it's this 18 specific ETH.MESH number, but I know the specific 19 TVT brochure is discussed in her report. But that's 20 the long way of saying no to your answer -- to the 21 question you asked earlier. 22 MR. GAGE: I've been burned before at 23 trial many times with experts saying, "Oh, yeah. I 24 reviewed and relied on this. It's not on any 25 document or listing that I've given you, but you</p>

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<p style="text-align: right;">Page 82</p> <p>1 should have asked the right question at the depo,"</p> <p>2 which is why I'm just -- I go overboard on asking</p> <p>3 those questions.</p> <p>4 MR. JONES: I get it. I think this one</p> <p>5 is talked about in her report.</p> <p>6 THE WITNESS: Yeah.</p> <p>7 BY MR. GAGE:</p> <p>8 Q. And so, Dr. Parisian, do you -- do you</p> <p>9 believe this is the document that you have</p> <p>10 specifically reviewed and discussed in your report?</p> <p>11 A. Yes, sir.</p> <p>12 Q. Okay.</p> <p>13 A. Yes, sir.</p> <p>14 Q. And on page -- I'll call it page 13 of the</p> <p>15 exhibit.</p> <p>16 A. Right.</p> <p>17 Q. And you'll see the page numbers there. You</p> <p>18 see what those page numbers are?</p> <p>19 A. Yeah. In my report, I talk about page 11</p> <p>20 and page 13 from this document.</p> <p>21 Q. All right. And I may be misquoting you. If</p> <p>22 I am, then the record will correct me, and the</p> <p>23 question will be stricken.</p> <p>24 But I thought I heard you say the patient</p> <p>25 brochure did not disclose any of the risks?</p>	<p style="text-align: right;">Page 84</p> <p>1 they're not saying, you have chronic risks, too,</p> <p>2 that are going to occur. It's not just something</p> <p>3 immediately postop.</p> <p>4 Q. Have you discussed this brochure with any</p> <p>5 TVT-Secur patient?</p> <p>6 A. No.</p> <p>7 Q. Have you conducted any surveys or studies of</p> <p>8 TVT-Secur patients as to their understanding of the</p> <p>9 reading of the TVT-Secur patient brochure?</p> <p>10 A. No. But this is based on my training and</p> <p>11 experience, looking at labeling as a physician and</p> <p>12 an FDA person who's been trained to do that.</p> <p>13 Q. Have you conducted a -- or have you -- I</p> <p>14 asked it -- I think I've already asked this, but I</p> <p>15 can't remember.</p> <p>16 Have you asked any pelvic floor surgeon</p> <p>17 about the TVT-Secur patient brochure?</p> <p>18 A. No.</p> <p>19 Q. Have you conducted a survey or study of</p> <p>20 pelvic floor surgeons about what they would</p> <p>21 understand the risks to be of the TVT-Secur</p> <p>22 procedure from reading the TVT-Secur patient</p> <p>23 brochure?</p> <p>24 A. What a physician would get out of it or what</p> <p>25 a patient?</p>
<p style="text-align: right;">Page 83</p> <p>1 A. Yes.</p> <p>2 Q. Okay. So we see on page 13 a paragraph that</p> <p>3 says, "What are the risks?" And it says, "All</p> <p>4 surgical procedures present some risks."</p> <p>5 Do you agree with that?</p> <p>6 A. Yes, but that's not telling them about this</p> <p>7 procedure.</p> <p>8 Q. All right. "Complications associated with</p> <p>9 the procedure include injury to blood vessels of the</p> <p>10 pelvis, difficulty urinating, pain, scarring, pain</p> <p>11 with intercourse, bladder and bowel injury."</p> <p>12 Do you see that?</p> <p>13 A. Yes, sir.</p> <p>14 Q. Now, is it your opinion that a patient</p> <p>15 contemplating a TVT-Secur implant who reads this</p> <p>16 patient brochure would not recognize those as risks</p> <p>17 of the TVT-Secur?</p> <p>18 A. No. They're thinking it's risks of the</p> <p>19 surgery. All surgical procedures present some</p> <p>20 risks, so they're talking about the acute phase of</p> <p>21 the surgery. They're not talking about the device.</p> <p>22 They're talking about the surgery.</p> <p>23 So if a patient was reading that, that's</p> <p>24 what they would take that home as, oh, okay. If I</p> <p>25 have my surgery, this is my potential risk. But</p>	<p style="text-align: right;">Page 85</p> <p>1 Q. Physician.</p> <p>2 A. Physicians, no, I haven't, but this is not</p> <p>3 made for a physician. It's made for a patient.</p> <p>4 Q. If a physician read this?</p> <p>5 A. Right. Does it say anything about the</p> <p>6 chronic complications? No.</p> <p>7 Q. Let me -- let me ask the question. Okay,</p> <p>8 Dr. Parisian?</p> <p>9 If a physician read this patient brochure</p> <p>10 and they read the sentence, "Complications</p> <p>11 associated with the procedure include injury to</p> <p>12 blood vessels of the pelvis," is it your testimony</p> <p>13 that a physician could only interpret that to mean</p> <p>14 that it is related to the procedure, not the mesh,</p> <p>15 and that it only can be acute and not chronic?</p> <p>16 A. Yeah.</p> <p>17 Q. Okay. Difficulty urinating?</p> <p>18 A. Right. Postop, they have difficulty</p> <p>19 urinating, so this is --</p> <p>20 Q. Let me pose the question.</p> <p>21 So a physician reading the phrase</p> <p>22 "difficulty urinating" could only interpret that to</p> <p>23 mean it is a risk of the procedure, not mesh, and it</p> <p>24 could only be acute and not chronic?</p> <p>25 MR. AYLSTOCK: Objection to form.</p>

22 (Pages 82 to 85)

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<p style="text-align: right;">Page 86</p> <p>1 MR. JONES: Objection.  2 THE WITNESS: That's the problem with  3 the way this is written. It talks about, "All  4 surgical procedures present some risk," and so when  5 it's talking about complications associated with the  6 procedure, they're not saying with the device, with  7 the implant. You're saying "with the procedure."  8 So a surgeon would be reading this --  9 and a patient which is more important because this  10 is for a patient -- is that these things would be  11 associated with the procedure; not the device.  12 And so these are things that occur from  13 that, not -- not the TVT-Secur.  14 BY MR. GAGE:  15 Q. All right. And as to the remainder of that  16 sentence that says "pain, scarring, pain with  17 intercourse, bladder and bowel injury," would the  18 same hold true in the sense that it is your opinion  19 that a surgeon reading those words would associate  20 those complications only with the procedure and not  21 with the mesh and would understand them to be only  22 acute and not chronic?  23 MR. AYLSTOCK: Objection to the form.  24 MR. JONES: Objection.  25 THE WITNESS: Well, this is written for</p>	<p style="text-align: right;">Page 88</p> <p>1 question about it, but we are getting into replowing  2 old ground at this time.  3 MR. GAGE: I gotcha. I understand your  4 position. All right.  5 So could you re-ask the question?  6 (Requested portion was read by the  7 Court Reporter.)  8 MR. AYLSTOCK: Objection to form.  9 THE WITNESS: And the answer is yes --  10 BY MR. GAGE:  11 Q. Okay.  12 A. -- which is what I said.  13 Q. So the next sentence says, "There's also a  14 risk of the mesh material becoming exposed."  15 A. Um-hmm.  16 Q. Do you see that?  17 A. Um-hmm.  18 Q. What does that communicate to a surgeon?  19 A. Postoperatively you could have exposure of  20 the mesh.  21 Q. What does it communicate to a patient?  22 A. To a patient? That you can have  23 complications right after your surgery.  24 Q. Is it your opinion that that sentence about  25 the risk of the mesh material becoming exposed</p>
<p style="text-align: right;">Page 87</p> <p>1 a woman. It's not written for a surgeon. But  2 there's nothing here that says these are chronic.  3 These conditions can occur postop, that they can  4 occur a long-term away.  5 So the way it's written is that these  6 complications would be something that a woman would  7 expect to see in the immediate postop period.  8 BY MR. GAGE:  9 Q. But my question was about a doctor, so could  10 you --  11 A. Well, he's the doctor. Remember, doctors  12 oftentimes don't see patients after the postop  13 period. They may see them maybe in a week or two  14 weeks and may never see them again.  15 See, this is saying that in your postop  16 course, you may see something like this, but it's  17 not saying that these women would have a chronic  18 problem.  19 MR. GAGE: Could you read back the  20 original question?  21 MR. AYLSTOCK: Before you do that, just  22 for the record, Dr. Parisian was questioned  23 extensively on the TVT-Secur patient brochure in her  24 prior deposition, so I just want to note that.  25 I'm not saying you can't ask another</p>	<p style="text-align: right;">Page 89</p> <p>1 refers only to immediate postop and not in the  2 long-term?  3 MR. AYLSTOCK: Objection to form.  4 THE WITNESS: That's the way it's  5 written. It's talking about that, and then exposure  6 may require treatment. What does that mean to a  7 patient? Well, it could mean -- it doesn't say, you  8 may need surgery to have the thing removed. It just  9 says "treatment."  10 A physician -- if you go back to your  11 physician, it could mean something in the office, as  12 opposed to you might need to take this thing out  13 which -- and you might need revision surgery.  14 That's not being conveyed there.  15 BY MR. GAGE:  16 Q. Did TVT-Secur -- or did surgeons who  17 implant -- strike that.  18 Did surgeons who implanted TVT-Secur know  19 that the mesh could erode before implanting?  20 A. You know, every surgeon that's going to have  21 a case, we're going to have the surgeon saying what  22 he knew. And the question is erode, whether they  23 needed to know that they're going to have surgery,  24 that they had to take it out, how frequently it was  25 eroding. All those things they didn't know.</p>

23 (Pages 86 to 89)



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<p style="text-align: right;">Page 90</p> <p>1 And most of them will testify that they 2 haven't known, or they didn't know that in terms of 3 the Garcia case that -- so each surgeon for every 4 case is going to talk about what they knew. 5 Q. Did you conduct any survey or any study of 6 either surgeons or literature in order to ascertain 7 what risks of TVT-Secur surgeons were aware of 8 generally when the device first came on the market? 9 A. No. That would have been -- I looked at the 10 sales documents, and so we actually had the sales 11 documents. What they're telling the doctor, that 12 this was going to be less invasive and that it was 13 going to be -- because you only had one -- one 14 incision, and that you could do either the egg 15 shaped or the U shaped. And so they're telling the 16 doctor that it's very easy, one incision, and that 17 doesn't go along with the product. 18 So, no, I didn't. But looking at this, what 19 are the risks, this is written for a patient, and 20 it's not talking about the long-term risks. It's 21 only talking about the risks of the surgery. 22 MR. JONES: I need to make a record 23 real quick on the brochure and the general agreement 24 that we hashed out prior to the depo and at the 25 beginning of the depo it was confirmed that you</p>	<p style="text-align: right;">Page 92</p> <p>1 I mean, I know it was covered, but I 2 was surprised to hear her say that, and that's why I 3 did it. 4 MR. JONES: Okay. And my response is 5 that I think you could have used what was already 6 covered in the prior deposition, then. 7 THE WITNESS: And I still hold that 8 opinion. And the risk information is still 9 inadequate. There's nothing here to tell the woman 10 about the chronic long-term risks that she's going 11 to have with this device. 12 MR. GAGE: And we don't need to debate 13 it further. 14 MR. JONES: It's the record. 15 BY MR. GAGE: 16 Q. The reason, Dr. Parisian, that I posed all 17 these questions to you is I think your testimony 18 was, there is no, meaning zero, risk information in 19 the patient brochure, and that is what I could not 20 let go unaddressed, and that's why I felt it was 21 necessary. 22 I do understand, admit, and recognize that 23 you've always taken the position that the patient 24 brochure is inadequate, but that was the first time 25 I heard you take the position --</p>
<p style="text-align: right;">Page 91</p> <p>1 weren't going to cover the same ground as the Garcia 2 case and the Garcia deposition that was taken in 3 February 2015. 4 And you said we'd both do our best 5 jobs, so here's my best job of ensuring that doesn't 6 happen. 7 This brochure that you just marked as 8 an exhibit and asked her, you know, quite a few 9 questions on was actually -- she was actually 10 questioned about it in her prior deposition. 11 A TVT-Secur brochure was actually 12 introduced as an exhibit at that prior deposition. 13 In fact, it looks like it's the same brochure that 14 you just used at this deposition. 15 So if we can do our best to not do that 16 again -- 17 MR. GAGE: I will. 18 MR. JONES: -- I would really 19 appreciate that. 20 MR. GAGE: If you'll notice, what 21 provoked it was the witness said, "There is no risk 22 information in the patient brochure." 23 I immediately reached over and got the 24 brochure, which I wasn't intending to use with her. 25 I couldn't let that statement go completely.</p>	<p style="text-align: right;">Page 93</p> <p>1 MR. JONES: And she talks about it in 2 her report, and it's addressed in her report under 3 risk, so if we can move on. But that's just -- my 4 point is if we can try our best not to, at the very 5 least, cover the exact same exhibits that were used 6 at the prior deposition -- 7 MR. GAGE: I understand. 8 MR. JONES: -- that would be great. 9 BY MR. GAGE: 10 Q. So, Dr. Parisian, what's the risk of erosion 11 with TVT-Secur known to the medical community in 12 2006? 13 A. 2006? Well, it wasn't known in terms of 14 2008 in terms of the risk of erosion. FDA was 15 trying to call for the information, even for the 16 single incision sling, so I don't think it was 17 known. 18 That it could occur, yes, but the risk and 19 how frequently it was occurring, the severity of it, 20 no, that was not known. 21 And that was what the -- all the stuff 22 happened in 2008 for the FDA to try to get some 23 information about that for women. 24 Q. Do you know what the earliest date in the 25 published medical literature is where the risk of</p>

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<p style="text-align: right;">Page 94</p> <p>1 erosion was discussed or identified as a risk of 2 stress urinary incontinence mesh? 3 A. Well, I know with ProtoGen it was discussed 4 back in '98. 5 Q. What about the risk of chronic dyspareunia 6 with stress urinary incontinence mesh? Do you know 7 when that risk was first discussed in the public 8 medical literature? 9 A. Well, that also was associated with 10 ProtoGen. The issue is that it was discussed in the 11 literature so, therefore, it was noticed for Ethicon 12 to know that this was a potential risk in anything 13 they designed. 14 Q. Do you know when the risk of chronic pain as 15 a risk of stress urinary incontinence mesh was first 16 discussed in the public medical literature? 17 A. I don't know when chronic pain was. 18 Q. I'm sorry? 19 A. I don't know the date for chronic pain. 20 Q. Did you discuss any sort of survey or 21 analysis of the published medical literature to 22 determine what risks, if any, of stress urinary 23 incontinence mesh were known to the medical 24 community as of, say, 2005 or 2006? 25 A. I've looked at various literature. No, I</p>	<p style="text-align: right;">Page 96</p> <p>1 these questions in the context of pelvic organ 2 prolapse, and now I'm going to pose these questions 3 in the context of stress urinary incontinence. 4 So they may sound the same as this morning, 5 but they are -- they are different because I'm going 6 from pelvic organ prolapse to stress urinary 7 incontinence. 8 A. Right. 9 And the answer basically is the same, 10 though, that a woman who would go in and get a 11 surgery from a urologist for stress urinary 12 incontinence before these transvaginal mesh usually 13 is a person that's had chronic problems and 14 symptoms, and so you didn't just lightly go in and 15 have these procedures done. 16 So when the transvaginal mesh came, the 17 issue was you had a brand new population, women that 18 stress urinary incontinence was all she had, and 19 that was just a symptom that may have been 20 uncomfortable when she was at a class in yoga. And 21 so some of these women didn't have much. 22 So in terms of risk versus benefit, they 23 shouldn't have any kind of risk of chronic 24 dyspareunia when they really had very little benefit 25 that they were going to get from these transvaginal</p>
<p style="text-align: right;">Page 95</p> <p>1 did not do a search. I mean, I've looked at 2 literature since the '90s, so, no, I did not do a 3 conducted search to look for when they knew certain 4 things. 5 I go back to the ProtoGen because I know 6 those were the risks that it was getting removed 7 from the market. So, therefore, to me, that's 8 notice for the industry that there was an issue with 9 ProtoGen, and it was a potential unacceptable risk. 10 Q. Dr. Parisian, is chronic pain with 11 intercourse a risk of non-mesh stress urinary 12 incontinence surgery? 13 A. I think we talked about that earlier today. 14 It depends, I mean, because in women who have the 15 non-mesh surgery, you know, the traditional things, 16 they usually are chronic patients anyway. They've 17 had problems. They've had multiple surgeries, and 18 so who knows. I don't know. 19 The question is, would chronic dyspareunia 20 have occurred to a woman who had minimal symptoms, 21 got an elective transvaginal mesh procedure, would 22 that be something you would expect in that patient? 23 No. 24 Q. All right. And just to be clear, the 25 questions we talked about this morning, I posed</p>	<p style="text-align: right;">Page 97</p> <p>1 mesh. 2 Q. All right. So I think the answer to the 3 question -- the question as posed was, is chronic 4 pain during intercourse a potential risk of non-mesh 5 SUI surgery, and I think your answer was yes. Is 6 that correct? 7 A. In the caveat that you had two totally 8 different populations. You had a population that 9 would have gone to surgery, traditional surgery, 10 versus a population with minimal symptoms as a rule 11 for SUI. And so you're comparing apples and 12 oranges. 13 You have a specific group, yes, they could 14 have chronic dyspareunia, but they are a different 15 starting group than the group that got the 16 transvaginal mesh. 17 Q. Well, I understand that, and I'm not asking 18 you to weigh the relative risks as between the mesh 19 group and the non-mesh group. 20 I'm just simply asking whether these could 21 be risks in the non-mesh group. 22 A. Yeah, but with the caveat, you have a 23 totally different population. 24 Q. Well, we'll -- I will stipulate for all of 25 these questions, they are two different populations.</p>



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<p style="text-align: right;">Page 98</p> <p>1 I'm not asking you to compare the two populations.  2 A. Right.  3 I will answer, yes, they will have that  4 risk, but with the caveat that we're talking totally  5 different, apples and oranges.  6 Q. Understood.  7 And so you would agree that chronic pain is  8 a risk of non-mesh SUI surgery?  9 A. It can be, yes, sir.  10 Q. Vaginal scarring is a risk of non-mesh SUI  11 surgery?  12 A. I don't know about vaginal scarring. I'll  13 leave that one as I don't know.  14 Q. Infection is a potential risk of a non-mesh  15 SUI surgery?  16 A. Infection can be a risk of almost any  17 surgery.  18 Q. And urinary problems, including urinary  19 frequency, retention, obstruction, urge  20 incontinence, and voiding dysfunction could be  21 potential risks of a non-mesh SUI surgery; correct?  22 A. Yes. And you're not talking in time frames  23 either, because you can have infection acute in  24 terms of postop, but would you see chronic infection  25 without a mesh? Probably not.</p>	<p style="text-align: right;">Page 100</p> <p>1 complications ever occur with a non-mesh SUI  2 surgery?  3 A. They can occur, yes.  4 Q. Can inflammation occur with a non-mesh SUI  5 surgery?  6 A. Inflammation? What kind of -- I mean, are  7 you talking about inflammation in terms of infection  8 or red, or what are you talking about?  9 Q. Inflammation of the human tissue.  10 A. It's kind of a generic term.  11 Q. If you can't answer the question, then you  12 can't answer it.  13 A. Yeah, it can occur, but it's just too  14 nonspecific.  15 Q. Can fistula formation occur with a  16 non-mesh SUI surgery?  17 A. It can occur.  18 Q. Can neuromuscular problems in the groin,  19 thigh, leg, pelvis, or abdominal area occur in a  20 non-mesh SUI surgery?  21 A. Yes.  22 Q. And is it sometimes necessary for one or  23 more surgeries to be conducted in order to treat an  24 adverse event arising out of a non-mesh SUI surgery?  25 A. It can be.</p>
<p style="text-align: right;">Page 99</p> <p>1 And so, you know, you're not qualifying who  2 the sick people are, and then we're also not putting  3 in the time frame, because infection is more postop  4 for a non-surgical mesh, whereas it's chronic in  5 women who have a surgical mesh, that their mesh gets  6 infected, so it's different.  7 Q. Understand.  8 Is organ or nerve damage a risk of non-mesh  9 SUI surgery?  10 MR. JONES: Objection.  11 THE WITNESS: It can be the same  12 caveat. And then you're talking about the  13 transobturator pap is usually the one who would see  14 the mesh with the nerve injury.  15 BY MR. GAGE:  16 Q. Is bleeding a risk of non-mesh SUI surgery?  17 A. Bleeding is a risk of any surgery acutely.  18 Q. Are wound complications a risk of non-mesh  19 SUI surgery?  20 A. Acutely, yes, sir.  21 Q. Not chronically?  22 A. Not typically chronically, no. You tend to  23 be acute postop, period.  24 Q. You used the word "typically."  25 Can wound complications -- can chronic wound</p>	<p style="text-align: right;">Page 101</p> <p>1 Q. Can a foreign body response be a risk of a  2 non-mesh SUI surgery if a foreign body is used?  3 A. Well, did they -- did they use a foreign  4 body? I mean, if they used a foreign body, yes.  5 Q. And we talked about this in the Prolift+M  6 deposition. I'm not sure it's absolutely necessary  7 that I re-ask it, but I don't want you to later say,  8 well, I was talking only about Prolift+M, so I'll  9 ask this question.  10 Well, no, I won't. I'll strike that.  11 Doctor, are you aware that some doctors did  12 not read the TVT-Secur IFU before implanting the  13 device?  14 A. You know, I think we talked about that  15 today. Yeah, some doctors may not. They may have  16 relied on the sales rep, the training, the course,  17 other things besides the IFU.  18 Q. Is it acceptable medical practice for a  19 pelvic floor surgeon to implant a Secur device  20 without first reading the IFU?  21 A. Well, they obviously have training in it,  22 and so where are they getting their training? The  23 IFU oftentimes drops into the surgical field, and  24 you're not going to sit there in the OR reading it.  25 So it depends. I mean, obviously they've had some</p>

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<p style="text-align: right;">Page 102</p> <p>1 training.</p> <p>2 Q. When and how often should surgeons read the</p> <p>3 IFU?</p> <p>4 A. Usually the sales reps are the ones who</p> <p>5 bring it to them and say, "Here. Read this," and</p> <p>6 they go through the different features of the</p> <p>7 product, and they go through telling them what they</p> <p>8 need to know. So an IFU is often interacted with</p> <p>9 the sales force.</p> <p>10 Q. How often should they read it? Should --</p> <p>11 strike that.</p> <p>12 How often should a surgeon read the</p> <p>13 TVT-Secur IFU?</p> <p>14 MR. AYLSTOCK: Objection. Form. Asked</p> <p>15 and answered.</p> <p>16 THE WITNESS: Well, the sales rep</p> <p>17 usually tells them if there's something new in it or</p> <p>18 if -- so they're interactive with the sales reps at</p> <p>19 the same time, so --</p> <p>20 BY MR. GAGE:</p> <p>21 Q. Let me change the question.</p> <p>22 A. Yeah.</p> <p>23 Q. I may have confused you.</p> <p>24 For purpose of this question, assume that</p> <p>25 the IFU does not change, that it's the same IFU.</p>	<p style="text-align: right;">Page 104</p> <p>1 risks from the TVT-Secur device they appreciate from</p> <p>2 the IFU?"</p> <p>3 BY MR. GAGE:</p> <p>4 Q. All right. Then I'll ask it like this:</p> <p>5 Doctor, since February of 2015, have you conducted</p> <p>6 any study or survey of pelvic floor surgeons to</p> <p>7 determine whether they ever read the Secur IFU?</p> <p>8 A. No.</p> <p>9 Q. Since February of 2015, have you conducted</p> <p>10 any study or survey of pelvic floor surgeons to</p> <p>11 determine what risks they understood as a result of</p> <p>12 reading the Secur IFU?</p> <p>13 A. No.</p> <p>14 Q. Have you conducted -- since -- I'm sorry.</p> <p>15 Strike that.</p> <p>16 Since February 2015, have you conducted any</p> <p>17 study or survey of pelvic floor surgeons who</p> <p>18 implanted Secur to determine what risks of the</p> <p>19 device they understood as a result of their medical</p> <p>20 school education?</p> <p>21 A. No.</p> <p>22 Q. Since February 2015, have you conducted any</p> <p>23 study or survey of pelvic floor surgeons who</p> <p>24 implanted Secur to determine what risks the device</p> <p>25 they understood as a result of their surgical</p>
<p style="text-align: right;">Page 103</p> <p>1 Do you have an opinion as to how often a</p> <p>2 surgeon should read that IFU?</p> <p>3 A. No.</p> <p>4 Q. Is there any regulatory standard that</p> <p>5 requires them to read the IFU?</p> <p>6 A. No. That's -- that's medical practice.</p> <p>7 That's not FDA.</p> <p>8 Q. Have you conducted any study or survey of</p> <p>9 pelvic floor surgeons to determine whether they read</p> <p>10 the Secur IFU?</p> <p>11 A. No.</p> <p>12 Q. Have you conducted any study or survey of</p> <p>13 pelvic floor surgeons to determine what risks they</p> <p>14 understood as a result of --</p> <p>15 MR. AYLSTOCK: You're now asking the</p> <p>16 exact question precisely that was asked in the prior</p> <p>17 deposition.</p> <p>18 MR. GAGE: Oh, wow.</p> <p>19 MR. AYLSTOCK: You're almost going off</p> <p>20 the same --</p> <p>21 MR. GAGE: What page are you on?</p> <p>22 MR. JONES: I mean, it's fair to say</p> <p>23 that the IFU brochure was covered at length in --</p> <p>24 MR. AYLSTOCK: Page 121, line 12, "Do</p> <p>25 you have any study or survey of doctors in what</p>	<p style="text-align: right;">Page 105</p> <p>1 training?</p> <p>2 A. No.</p> <p>3 Q. Since February 2015, have you conducted any</p> <p>4 study or survey of pelvic floor surgeons who</p> <p>5 implanted Secur to determine what risks of the</p> <p>6 device they understood as a result of reading</p> <p>7 relevant medical literature?</p> <p>8 A. No.</p> <p>9 Q. Should pelvic floor surgeons implanting</p> <p>10 Secur read the medical literature about the device?</p> <p>11 A. Yeah, I don't have an opinion about that. I</p> <p>12 mean, they're responsible for their practice.</p> <p>13 Q. Could doctors have learned of the risks of</p> <p>14 TVT-Secur from reading medical literature?</p> <p>15 MR. JONES: Objection.</p> <p>16 THE WITNESS: More likely they would</p> <p>17 have been able to learn it from Ethicon than in the</p> <p>18 literature.</p> <p>19 BY MR. GAGE:</p> <p>20 Q. But could they learn of risks from reading</p> <p>21 the TVT-Secur literature?</p> <p>22 MR. JONES: Objection.</p> <p>23 THE WITNESS: They could if there was</p> <p>24 such literature out there.</p> <p>25 ///</p>

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<p style="text-align: right;">Page 106</p> <p>1 BY MR. GAGE:</p> <p>2 Q. With regard to the literature that you</p> <p>3 reviewed in connection with your TVT-Secur report in</p> <p>4 the MDL, is it fair to say that the literature you</p> <p>5 reviewed would be included either as a citation in</p> <p>6 your report itself or in your reliance list or in</p> <p>7 this document marked as Exhibit 6 or otherwise</p> <p>8 marked as one of the exhibits at this deposition?</p> <p>9 A. I believe so.</p> <p>10 MR. JONES: Objection.</p> <p>11 If you want me to explain, I will.</p> <p>12 MR. GAGE: Yes. Give me -- explain</p> <p>13 your objection.</p> <p>14 MR. JONES: And this goes back to</p> <p>15 earlier today.</p> <p>16 You're going to be asking about</p> <p>17 literature, and that was why I got hung up. You</p> <p>18 kept using the word "documents," and I kept bugging</p> <p>19 you and being annoying about internal documents.</p> <p>20 I'm sure that was very annoying.</p> <p>21 MR. GAGE: Actually, it wasn't. You've</p> <p>22 been -- you're not bothering me.</p> <p>23 MR. JONES: The literature -- you know,</p> <p>24 lots of times Ethicon -- you know, this literature</p> <p>25 will be listed under ETH.MESH number, you know, and</p>	<p style="text-align: right;">Page 108</p> <p>1 MR. AYLSTOCK: And just to be clear,</p> <p>2 again, there's extensive questioning on her reliance</p> <p>3 list and the scientific literature in the prior</p> <p>4 deposition. And in particular, the Cochrane report</p> <p>5 and others, so I think we're really --</p> <p>6 MR. GAGE: I'm limiting my question to</p> <p>7 the literature she's reviewed for her TVT-Secur MDL</p> <p>8 report.</p> <p>9 MR. JONES: I think she's already said</p> <p>10 it's essentially the same.</p> <p>11 MR. GAGE: All right. So let me ask</p> <p>12 that question. I don't think I've asked that</p> <p>13 question.</p> <p>14 BY MR. GAGE:</p> <p>15 Q. Since your disclosure and deposition in the</p> <p>16 TVT-Secur case in the Garcia matter, have you</p> <p>17 reviewed any additional or new medical literature</p> <p>18 pertinent to TVT-Secur?</p> <p>19 A. No.</p> <p>20 Q. So whatever TVT-Secur literature may have</p> <p>21 come out since February of 2015, you would not have</p> <p>22 reviewed it. Is that correct?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. Since February 2015, have you</p> <p>25 conducted any study or survey of pelvic floor</p>
<p style="text-align: right;">Page 107</p> <p>1 there's clinical expert reports. There's FDA</p> <p>2 literature. There's Cochrane.</p> <p>3 And so what I don't want to get in a</p> <p>4 situation of is someone just going through the</p> <p>5 reliance list and saying, gotcha. This one isn't on</p> <p>6 there. And then, well, it's in the clinical expert</p> <p>7 report that is in the box that you had for, you</p> <p>8 know, a year.</p> <p>9 Or, gotcha. It's not on your reliance</p> <p>10 list. I got -- I handed you in the depo. You made</p> <p>11 a reliance list under literatures, all the</p> <p>12 literature reviewed. But, oh, wait. It's listed in</p> <p>13 the -- you know, as an ETH.MESH Bates number because</p> <p>14 there was an e-mail sent with three articles</p> <p>15 attached.</p> <p>16 That's what -- to me, the objection is</p> <p>17 so I have an opportunity to explain it at a later</p> <p>18 point if this becomes an issue that, oh, here's the</p> <p>19 same article. Why isn't it in the literature tab on</p> <p>20 the reliance list, but it was in the box, or it was</p> <p>21 in the report or it was in the clinical expert</p> <p>22 report or it was part of the Cochrane or it's part</p> <p>23 of the literature review that she talked about.</p> <p>24 So that's my objection.</p> <p>25 MR. GAGE: Got it.</p>	<p style="text-align: right;">Page 109</p> <p>1 surgeons who implanted Secur to determine what risks</p> <p>2 of the device they understood as a result of their</p> <p>3 experience implanting other mesh devices?</p> <p>4 A. No.</p> <p>5 Q. Since February 2015, have you conducted any</p> <p>6 study or survey of pelvic floor surgeons who</p> <p>7 implanted Secur to determine what risks they</p> <p>8 understood as a result of participating in any</p> <p>9 training on Secur?</p> <p>10 A. No.</p> <p>11 Q. Since February 2015, have you conducted any</p> <p>12 study or survey of pelvic floor surgeons who</p> <p>13 implanted Secur to determine what risks they</p> <p>14 understood as a result of participating in</p> <p>15 Ethicon-sponsored training on Secur?</p> <p>16 A. No.</p> <p>17 MR. JONES: Form.</p> <p>18 MR. AYLSTOCK: Let me just say,</p> <p>19 William, if we're going to preface every question</p> <p>20 that was already asked in the prior deposition with,</p> <p>21 "Since the prior deposition," then I'm going to</p> <p>22 insist on taking every one of your experts again</p> <p>23 because their depositions were done months or years</p> <p>24 ago. And I'll ask every question starting with,</p> <p>25 "Since," and that will cure the problem.</p>

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<p style="text-align: right;">Page 110</p> <p>1 So, I mean, really none of the 2 questions you're asking are on the e-mail where you 3 specifically said, "Here's some new things I would 4 like to ask about." They're just fishing, so it's 5 really getting far afield. 6 MR. GAGE: I understand your objection. 7 And my concern is that I got a 115-page 8 report, I had a five-page disclosure, and then 9 there's been a year -- there's been a year 10 in-between. And I don't know what you guys have 11 asked her to do or examine or look at or what she's 12 done in that intervening year. 13 MR. AYLSTOCK: But all of her opinions 14 are in her report. You know, Judge Goodwin is going 15 to insist that her report is the end all, be all of 16 what her testimony is going to be. 17 So, again, it's not in her report that 18 she did any sort of survey. We're just in my view 19 reploting old ground, and that's not what I thought 20 we were going to be doing. 21 But go ahead. I'm not telling her not 22 to answer or anything. I'm just making my record. 23 MR. GAGE: I'm actually finished with 24 that line of questioning. 25 MR. AYLSTOCK: I'm glad I made the</p>	<p style="text-align: right;">Page 112</p> <p>1 A. The ones that I gave you today? 2 Q. Yes. 3 A. No. 4 Q. Okay. There have also been some additional 5 public pronouncements by FDA with regard to surgical 6 mesh; correct? 7 A. Yes. 8 Q. Okay. So I'm not trying to be duplicative 9 of prior questions, but new materials have come to 10 light -- 11 A. Right. 12 Q. -- and I feel compelled to ask you these 13 questions. 14 Has anything in these new materials that 15 you've examined led you to believe that FDA ever 16 recommended any labeling changes for Secur after it 17 was cleared? 18 A. No. 19 Q. Has FDA ever determined that the Secur 20 labeling was false or misleading? 21 MR. JONES: Objection. 22 You're tying this to specifically those 23 new documents, or are you asking generally? 24 MR. GAGE: Yeah, to the new documents. 25 I mean, I haven't looked at --</p>
<p style="text-align: right;">Page 111</p> <p>1 record when I did. 2 MR. JONES: Yeah. It worked. 3 MR. AYLSTOCK: Either it worked or I 4 was one question too late. 5 MR. GAGE: All right. Now, these are 6 questions that I have to ask the witness about since 7 February of 2015 because new things have occurred, 8 including things that have occurred after her report 9 was written. 10 MR. AYLSTOCK: Okay. 11 MR. GAGE: And I have to ask -- I'm not 12 trying to be duplicative. 13 MR. AYLSTOCK: I'm not trying to be 14 obstructive. 15 MR. GAGE: Truly, I just -- I have to 16 make sure that I don't get blindsided with this. 17 BY MR. GAGE: 18 Q. And so here's the question, for example. I 19 know that there have been -- since the time of your 20 MDL expert report was written, you've looked at new 21 documents from FDA that were obtained by -- through 22 some Freedom of Information request; correct? 23 A. Um-hmm, yes. 24 Q. Had you looked at those at the time of the 25 Garcia deposition?</p>	<p style="text-align: right;">Page 113</p> <p>1 MR. JONES: That's not how your 2 question was phrased. That's my objection. 3 MR. GAGE: Well, I prefaced the -- 4 MR. JONES: So every question from 5 hereon after is limited to those two new documents? 6 MR. GAGE: I'll tell you what. Why 7 don't we do this. With regard to the -- I'm going 8 to ask you a series of questions with regard to the 9 new information that you have been provided since 10 the time of your Garcia deposition, and then when I 11 finish that sequence of questions, I'll announce it 12 so that that condition no longer applies to that 13 question, or do you want me to just put it in the 14 question? 15 MR. JONES: Yeah, I want it in the 16 question. 17 MR. GAGE: Okay. 18 BY MR. GAGE: 19 Q. Have you seen anything since your deposition 20 in the Garcia case in February 2015 that would lead 21 you to believe that the FDA determined that the 22 Secur labeling was false or misleading? 23 A. Well, in terms of those are regulatory 24 terms, and so are you saying that I've seen a 25 document where the FDA came out and said that?</p>

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<p style="text-align: right;">Page 114</p> <p>1 Cause then there's internally discussions, but  2 there's not a document where they said that the  3 label is false and misleading, other than, how did  4 this product get on the market, and some of the  5 issues with it and so -- but there's no specific  6 pronouncement that they said that.  7 Q. All right. Let me follow up.  8 You just said, other than how did  9 this document -- how did this device get on the  10 market?  11 A. Well, yes. When you look at the document  12 that I gave you in terms of the FDA's discussion  13 internally about mesh in general, there's --  14 there's --  15 Q. Do you have that document?  16 MR. JONES: It's in the box. Right  17 corner, I think.  18 BY MR. GAGE:  19 Q. Oh, this one?  20 A. Yeah.  21 Q. Let's make sure we're talking about the  22 right document.  23 Are we talking about the collection of  24 documents received --  25 A. Right.</p>	<p style="text-align: right;">Page 116</p> <p>1 TVT-Secur. And then the other guidance document or  2 the other reclassification, they talk about  3 TVT-Secur. So there are places where they mention  4 it and Prolift.  5 I mean, that focus of that package is on  6 Ethicon. They weren't looking at any other  7 manufacturer. They were looking at Prolift and  8 TVT-Secur.  9 Q. Do you know why that was the case?  10 A. No. FDA chose to go -- they apparently had  11 gotten some reports to Office of Compliance, and  12 they were looking at -- I believe they were looking  13 originally at hernia and got -- Ethicon's a big  14 group in terms of hernia repair, and then they  15 segued into transvaginal mesh.  16 Q. Did -- if having now reviewed the documents  17 in Exhibit 7 now that your MDL report is -- well,  18 you reviewed the documents in Exhibit 7 after your  19 MDL report came out; correct?  20 A. Yes, sir.  21 Q. Do you intend to write a supplement to  22 address these documents?  23 A. No, sir.  24 Q. Can you tell me how these documents support  25 or refute your opinions?</p>
<p style="text-align: right;">Page 115</p> <p>1 Q. -- from the public records request?  2 A. Right.  3 Q. All right. So that's Parisian TVT-Secur  4 Deposition Exhibit No. 7?  5 A. Right.  6 So there's discussion in there how the  7 FDA -- how did something get approved for  8 transvaginal insertion. And so FDA's going back and  9 forth trying to figure out, how did that happen.  10 And then they talk about, they're looking  11 for unsubstantiated claims. We don't know what  12 happened with that. So, I mean, they're actually  13 looking at stuff like that, and I don't know what  14 the conclusions were.  15 But in terms of the advisory group here,  16 that they were looking at the labeling. They were  17 looking at how products got on the market, like the  18 Prolift. They knew that the Prolift had been on  19 without any clearance, so there's actually internal  20 discussion by the FDA as to what they knew. But  21 they didn't say false and misleading.  22 Q. Is there anything in the -- in Exhibit 7  23 that pertains specifically to TVT-Secur?  24 A. I believe they talk about TVT-Secur in  25 there. They talk about Prolift. They talk about</p>	<p style="text-align: right;">Page 117</p> <p>1 A. They complete the picture of what I thought  2 was going on, that there actually had been  3 decisions -- I've been on committees like this where  4 you have a problem, and then you're trying to figure  5 out how to deal with it from the FDA's point of  6 view.  7 And so it just kind of tops off what I  8 thought was occurring. I think I had seen in other  9 documents that the FDA had created a group to look  10 at some of these things.  11 So it just -- it's just -- it makes it much  12 more complete. Why did the FDA come out with a  13 public health notification? That really discusses  14 why.  15 Q. What is the date?  16 A. 2007, 2008, so it's before the public health  17 notification in October 2008.  18 Q. Is it before the -- when was the TVT-Secur  19 510(k) cleared?  20 A. Oh, gosh. 2000- -- wasn't that around 2007?  21 So we're talking about the same time frame.  22 Q. Do you know any of the individuals on the  23 surgical mesh action team?  24 A. Some of them I do.  25 Q. All right. So you're not intending on</p>



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<p style="text-align: right;">Page 118</p> <p>1 writing a supplement based on these documents?</p> <p>2 A. I haven't been asked to do that. So let's</p> <p>3 see. I think it was around -- TVT-Secur --</p> <p>4 Q. So --</p> <p>5 A. It was November 30, 2005, so this actually</p> <p>6 was occurring after TVT-Secur had been on the</p> <p>7 market.</p> <p>8 Q. All right. So is there anything in that</p> <p>9 Exhibit No. --</p> <p>10 MR. JONES: Seven -- six -- seven.</p> <p>11 BY MR. GAGE:</p> <p>12 Q. -- where FDA makes any conclusion as to</p> <p>13 whether the TVT-Secur labeling was false or</p> <p>14 misleading?</p> <p>15 A. Well, basically, when they're talking about</p> <p>16 the MDRs and the reports they're receiving, they</p> <p>17 know that the labels don't have that. And so that</p> <p>18 technically would be, you know, false -- false and</p> <p>19 misleading in terms of the FDA to try to get the</p> <p>20 information out to the public.</p> <p>21 And that's one of the reasons they're trying</p> <p>22 to do a Section 522 postmarketing study, so they</p> <p>23 could update the information for the user.</p> <p>24 So basically you would pursue something like</p> <p>25 this or you think that the literature for this --</p>	<p style="text-align: right;">Page 120</p> <p>1 illegally marketed?</p> <p>2 A. Illegally marketed, no, but there is a</p> <p>3 conclusion that the FDA is going to call for 522</p> <p>4 studies. 522 studies by definition would be that</p> <p>5 there's not enough postmarketing information, and</p> <p>6 that would include TVT-S, and that would include all</p> <p>7 the other TVT products.</p> <p>8 So does that answer your question?</p> <p>9 Q. Is that tantamount to a declaration that</p> <p>10 TVT-Secur was illegally marketed?</p> <p>11 A. I didn't say it was illegally marketed. It</p> <p>12 was marketed under a 510(k). What was illegal about</p> <p>13 it was it wasn't performing the way it was cleared,</p> <p>14 so it was a prohibited act because it wasn't</p> <p>15 fulfilling what was said in the 510(k).</p> <p>16 Q. And I'm just -- my opinions are limited to</p> <p>17 just that particular exhibit --</p> <p>18 A. Right.</p> <p>19 Q. -- because that's something that you got</p> <p>20 after you wrote your FDA -- I'm sorry -- after you</p> <p>21 wrote your TVT-Secur opinion.</p> <p>22 A. Yes.</p> <p>23 Q. And I just want to make sure that nothing in</p> <p>24 that document in your opinion constitutes a finding</p> <p>25 or declaration by FDA that TVT-Secur was illegally</p>
<p style="text-align: right;">Page 119</p> <p>1 they look at GYNEMESH, TVT, that the labeling is not</p> <p>2 reflecting the information that they're seeing in</p> <p>3 their medical device reports.</p> <p>4 Q. Let me change the question. Does that</p> <p>5 document you're holding in your hand hold a</p> <p>6 determination or final conclusion by FDA that the</p> <p>7 TVT-Secur labeling was false or misleading or</p> <p>8 inadequate?</p> <p>9 A. They're looking at all the transvaginal</p> <p>10 mesh, not specifically for the TVT-Secur, because</p> <p>11 you're asking me specifically about that?</p> <p>12 Q. That's correct.</p> <p>13 A. No. They were looking at the entire group</p> <p>14 of products as not having adequate information for</p> <p>15 the -- for the physician and the patient.</p> <p>16 Q. Is there anything in that document that</p> <p>17 constitutes a final determination by FDA that the</p> <p>18 TVT-Secur device was misbranded or adulterated?</p> <p>19 A. No. You won't see that in here.</p> <p>20 Q. Is there any conclusion or determination by</p> <p>21 the FDA that Ethicon failed to provide FDA with</p> <p>22 relevant safety information about TVT-Secur?</p> <p>23 A. No.</p> <p>24 Q. Is there anything in that document that is a</p> <p>25 conclusion or finding by FDA that the TVT-Secur was</p>	<p style="text-align: right;">Page 121</p> <p>1 marketed.</p> <p>2 A. No. I wouldn't expect -- I mean, it's not</p> <p>3 the FDA's job under 510(k). It would be the</p> <p>4 company's to say that the product is not marketed</p> <p>5 because it's not performing the way it's supposed</p> <p>6 to.</p> <p>7 I mean, the FDA's big thing is something</p> <p>8 needs to be done. They need post-market</p> <p>9 surveillance. They need some information out there.</p> <p>10 They need post-market studies.</p> <p>11 So the FDA is trying to correct the issue</p> <p>12 for the public. Not necessarily to -- they're not</p> <p>13 focusing on just TVT-S.</p> <p>14 Q. Dr. Parisian, several times -- well, a</p> <p>15 number of times in your TVT-Secur MDL report, you</p> <p>16 indicate that Ethicon withheld certain information</p> <p>17 from FDA.</p> <p>18 A. I think what I said was they didn't</p> <p>19 completely disclose the issues that were occurring</p> <p>20 so that FDA could consider what was going on and ask</p> <p>21 for new additional information.</p> <p>22 Q. All right. So I've got phrases throughout</p> <p>23 your report, and I'm just quoting one. I think it's</p> <p>24 Paragraph 228, where you say, "Ethicon did not fully</p> <p>25 and accurately disclose certain information."</p>



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<p style="text-align: right;">Page 122</p> <p>1 A. Yeah. That's like what I just said.</p> <p>2 Q. And then in another place in your MDL</p> <p>3 report, you opine that, quote, Ethicon withheld key</p> <p>4 information that was necessary for FDA to determine</p> <p>5 whether clearance of the 510(k) should occur?</p> <p>6 A. Yes. That means it was not in the</p> <p>7 application, and it was something they would have</p> <p>8 had.</p> <p>9 Q. Now, Dr. Parisian, it would -- it would be</p> <p>10 extraordinarily time-consuming for us to go through</p> <p>11 the report and identify each and every place where</p> <p>12 you have a phrase that is either identical or</p> <p>13 similar, i.e., Ethicon did not fully and accurately</p> <p>14 disclose, Ethicon withheld, et cetera.</p> <p>15 I think it's fair to say -- and I think you</p> <p>16 agree with me -- that phrases -- those words or</p> <p>17 phrases similar to those words appear frequently in</p> <p>18 your report. Is that fair?</p> <p>19 A. Well, if you go to the Paragraph 228, I</p> <p>20 specifically say what I'm talking about in terms --</p> <p>21 I mean, I don't just say that lightly. I go on and</p> <p>22 I talk about that the 510(k) didn't really tell the</p> <p>23 difference between a TVT and a TVT-O, and there was</p> <p>24 no way somebody could under- -- you know, determine</p> <p>25 that the TVT-S was totally different.</p>	<p style="text-align: right;">Page 124</p> <p>1 withheld information from the FDA?</p> <p>2 A. I don't know why they did it. I mean, it's</p> <p>3 just a fact that certain information wasn't put in</p> <p>4 there that I think should be important information.</p> <p>5 They could be the stupidest people in the world.</p> <p>6 That might have been it. They could -- so who knows</p> <p>7 why they did it. It's just a fact that that</p> <p>8 information wasn't there, and if I was writing a</p> <p>9 510(k), I would have included it.</p> <p>10 Q. Could it have been a difference of -- a good</p> <p>11 faith difference of opinion between you and the</p> <p>12 Ethicon employees?</p> <p>13 A. I don't know. I mean, let the courts</p> <p>14 decide.</p> <p>15 It's like that one truthful and accurate</p> <p>16 statement, I don't know why they always wrote it a</p> <p>17 different way. Somebody made them write it a</p> <p>18 different way. Someone told them to do it. Who</p> <p>19 knows? I don't know why they did it.</p> <p>20 But when you go through the 510(k), those</p> <p>21 are the things that you see that you think somebody</p> <p>22 should have told the FDA about. If I was a</p> <p>23 reviewer, I would have wanted to know.</p> <p>24 Q. So I'm trying to understand -- like when you</p> <p>25 use phrases like "Ethicon withheld key information,"</p>
<p style="text-align: right;">Page 123</p> <p>1 So, I mean, I go on, and then I talk about</p> <p>2 the French data, and so I'm usually giving specific</p> <p>3 examples. I don't just say -- I'm telling you what</p> <p>4 I think they withheld.</p> <p>5 Q. Right. And I wasn't suggesting that you</p> <p>6 didn't do that.</p> <p>7 I'm just asking you that -- to agree, if you</p> <p>8 want to, that there are a number of places in your</p> <p>9 MDL report where the sentence contains phrases like</p> <p>10 "Ethicon did not fully and accurately disclose</p> <p>11 certain pieces of information" --</p> <p>12 A. Right.</p> <p>13 Q. -- or "Ethicon withheld certain pieces of</p> <p>14 information."</p> <p>15 Would you agree with that?</p> <p>16 A. Yes, and then I give the information, why is</p> <p>17 it important in terms of the reviewer, because the</p> <p>18 whole thing is to trigger if there's new issues of</p> <p>19 safety and effectiveness.</p> <p>20 Q. Right.</p> <p>21 A. And so if they don't have that information,</p> <p>22 then they can't ask for additional testing.</p> <p>23 Q. All right. My question to you is, with</p> <p>24 regard to anything in your MDL report, is it your</p> <p>25 opinion that Ethicon at any place intentionally</p>	<p style="text-align: right;">Page 125</p> <p>1 I'm trying to understand, do you have evidence of</p> <p>2 intent to withhold?</p> <p>3 A. No. It's just not in the 510(k).</p> <p>4 Q. Okay. And that would hold true for not just</p> <p>5 Paragraph 228 but for the entirety of your report</p> <p>6 where you have an opinion that Ethicon did not fully</p> <p>7 and accurately disclose certain information or that</p> <p>8 Ethicon withheld information, in all of those</p> <p>9 instances or in none of those instances, is it</p> <p>10 correct to say that you have evidence of actual</p> <p>11 intent?</p> <p>12 MR. AYLSTOCK: Object to the form of</p> <p>13 the question.</p> <p>14 THE WITNESS: If indeed the company has</p> <p>15 a statement or e-mail or something that says why</p> <p>16 they did something, then I would give that.</p> <p>17 But if I don't have something to tell</p> <p>18 me what their intent was, then I'm just going to</p> <p>19 leave it general. Let the court decide.</p> <p>20 But if I -- there are times when the</p> <p>21 company -- company says, we're doing this. This is</p> <p>22 what our strategy is going to be. Well, that would</p> <p>23 be intent, that I can say, but if I don't have</p> <p>24 information to support it, I usually just leave it,</p> <p>25 it's not there.</p>

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<p style="text-align: right;">Page 126</p> <p>1 BY MR. GAGE:</p> <p>2 Q. Okay. And I think with regard to the</p> <p>3 internal e-mails where they may have declared their</p> <p>4 intent, did you find any internal e-mails or other</p> <p>5 company documents where, in your opinion, Ethicon</p> <p>6 consciously attempted to defraud the FDA?</p> <p>7 MR. JONES: Objection.</p> <p>8 THE WITNESS: That's not something I</p> <p>9 would talk about. I mean, because, I mean, there</p> <p>10 are things where the company has made a decision</p> <p>11 what they're going to do in terms of marketing, what</p> <p>12 they want in terms of marketing share.</p> <p>13 That would be -- you know, their intent</p> <p>14 so to sell products, but defraud the FDA, that</p> <p>15 sounds like a legal conclusion, and I don't make</p> <p>16 legal conclusions.</p> <p>17 BY MR. GAGE:</p> <p>18 Q. Well, let me ask you this: Did you find any</p> <p>19 e-mails that, in your opinion, state, "We, Ethicon,</p> <p>20 are going to not share this with the FDA so that</p> <p>21 they will not know what we know"?</p> <p>22 MR. JONES: Objection.</p> <p>23 THE WITNESS: I don't recall. I'm not</p> <p>24 going to say no. I'm not -- I just -- I don't</p> <p>25 recall at this moment in time because there are</p>	<p style="text-align: right;">Page 128</p> <p>1 issue reports or product complaint reports that it</p> <p>2 should have reported to FDA but didn't?</p> <p>3 A. I haven't done that review, so I don't</p> <p>4 intend to do it. Someone may ask me to do it, but I</p> <p>5 haven't done it.</p> <p>6 Q. Okay. So you don't have, for example, a</p> <p>7 list of either specific complaints or specific</p> <p>8 instances that you saw in the Ethicon documents and</p> <p>9 then you went to the MAUDE database, and you didn't</p> <p>10 find an instance that you felt should have been</p> <p>11 reported, and you would come to a jury and say,</p> <p>12 "Ladies and gentlemen of the jury, here are whatever</p> <p>13 the number of internal complaints or issue reports</p> <p>14 that they should have reported to the FDA. I went</p> <p>15 to the MAUDE database, I checked it, and they didn't</p> <p>16 do that"?</p> <p>17 A. No. I would look at the company documents</p> <p>18 looking for what they're receiving as reports, but I</p> <p>19 haven't done that in terms of the MDRs.</p> <p>20 Q. Okay. In your report, you indicate that --</p> <p>21 and I'm talking about your MDL report -- that the</p> <p>22 FDA's 510(k) process -- and I'm using your words --</p> <p>23 the FDA's 510(k) process admittedly has weaknesses,</p> <p>24 including FDA's required reliance of the</p> <p>25 truthfulness and accuracy of the information in the</p>
<p style="text-align: right;">Page 127</p> <p>1 things where they talk about the FDA and their</p> <p>2 strategy with the FDA. If I saw such a document, it</p> <p>3 would be in my report.</p> <p>4 MR. AYLSTOCK: Can we take a quick</p> <p>5 break whenever you get a chance?</p> <p>6 (Recess taken.)</p> <p>7 BY MR. GAGE:</p> <p>8 Q. All right. Dr. Parisian, we're back on the</p> <p>9 record.</p> <p>10 Have you endeavored to undertake an analysis</p> <p>11 of any of the TVT-Secur MAUDE reports?</p> <p>12 A. No.</p> <p>13 Q. Have you undertaken any analysis of the</p> <p>14 TVT-Secur issue reports at Ethicon?</p> <p>15 A. The issue reports in terms of the</p> <p>16 manufacturing.</p> <p>17 Q. Let me withdraw that question --</p> <p>18 A. Okay.</p> <p>19 Q. -- and let me get straight to it.</p> <p>20 I didn't see the report -- I didn't see this</p> <p>21 opinion in your MDL report, but I just want to make</p> <p>22 sure, as with Dr. Pence, it's not somewhere lurking</p> <p>23 out there for me.</p> <p>24 Do you intend for TVT-Secur to offer any</p> <p>25 opinion that Ethicon was in possession of certain</p>	<p style="text-align: right;">Page 129</p> <p>1 sponsor's premarketing application.</p> <p>2 A. Yes.</p> <p>3 Q. Do you remember that?</p> <p>4 A. Yes.</p> <p>5 Q. Because of the way it's worded, i.e., the</p> <p>6 process admittedly has weaknesses including --</p> <p>7 A. Um-hmm.</p> <p>8 Q. -- and you point out the FDA's required</p> <p>9 reliance of the truthfulness and accuracy portion,</p> <p>10 are there other weaknesses, in your opinion, of the</p> <p>11 510(k) process?</p> <p>12 A. One is you have a reliance on pre-amendment</p> <p>13 biomaterials. Our country tends to only get things</p> <p>14 approved or cleared that have been on the market</p> <p>15 since pre-'76. So inadvertently the 510(k) is</p> <p>16 locked. This is the pre-1976 mentality for</p> <p>17 materials where the rest of the world may use other</p> <p>18 materials, and so I think that's one of the</p> <p>19 weaknesses of the 510(k) process.</p> <p>20 Also, the idea that everything is</p> <p>21 grandfathered from the pre-amendment devices in the</p> <p>22 '90s, that -- that's got some flaws in it.</p> <p>23 Q. Let me interrupt you and be more precise</p> <p>24 with my question.</p> <p>25 In your opinion, does the FDA 510(k) process</p>

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<p style="text-align: right;">Page 130</p> <p>1 have any weaknesses that would be pertinent to 2 TVT-Secur?</p> <p>3 A. Yeah. Because in one of the things, the FDA 4 510(k) process is required to use the least 5 burdensome methods, and so manufacturers can cite 6 something else being cleared, like the Dura Patch, 7 and that is a cleared device in a neurological 8 indication.</p> <p>9 And so because it is cleared, Johnson &amp; 10 Johnson can then use it in a new intended use, and 11 they can -- they can just cite the 510(k). They 12 don't necessarily need to go out and provide the FDA 13 with data.</p> <p>14 FDA is bound to just the least burdensome, 15 so the FDA can't really ask for more testing.</p> <p>16 Even when -- what is it? -- TVT-Secur, when 17 Dr. Herrera asked for a clinical study for a 18 12-months data, they came in with a 510(k) for the 19 Gynecare Tape, and FDA then can't ask because they 20 had already cleared a device that was a mini tape 21 type thing. So there's limitation to what the FDA 22 can do based on the 510(k) process.</p> <p>23 And then also now we have the MDUFA user 24 fees, which they have only 90 days to get a 510(k) 25 done, which is actually a fairly quick turnaround</p>	<p style="text-align: right;">Page 132</p> <p>1 the FDA was told it's less invasive because there's 2 only one incision, but that doesn't mean it's less 3 invasive. That means it can be even more difficult 4 to put in, but the FDA accepted that Ethicon said it 5 was less invasive, and there really wasn't any data 6 to support that.</p> <p>7 Q. All right. So I want to stay focused on the 8 process, not so much --</p> <p>9 A. TVT-S?</p> <p>10 Q. Your statement in the report was the 510(k) 11 process has weaknesses --</p> <p>12 A. Right.</p> <p>13 Q. -- and you moved on to a discussion of --</p> <p>14 A. TVT-S?</p> <p>15 Q. Well, let me finish.</p> <p>16 I want -- I would like for you to identify, 17 and maybe you've already done it fully, but I would 18 like for you to identify any weaknesses in the 19 510(k) process that are pertinent to the TVT-Secur.</p> <p>20 A. I was trying to do that.</p> <p>21 Q. Well, let me make a distinction.</p> <p>22 When you said that FDA accepted Ethicon's 23 statement that TVT-Secur was less invasive, I don't 24 view that as part of the -- I'm talking about the 25 organizational structure of the 510(k) process --</p>
<p style="text-align: right;">Page 131</p> <p>1 time.</p> <p>2 And so there's -- there's things about the 3 FDA process to try to get new products in the market 4 for the public that make it difficult for the FDA 5 reviewer to get more data.</p> <p>6 They have -- it's easier to clear stuff than 7 to not clear it.</p> <p>8 Q. Are there any -- are there any additional 9 weaknesses of the 510(k) process that you perceive 10 that are pertinent to TVT-Secur?</p> <p>11 A. Well, in this particular case, the issue is 12 that the FDA was clearing transvaginal mesh as 13 basically surgical mesh, and they weren't asking for 14 any clinical data. They were just basically using a 15 checklist. You know, what is the porosity? What 16 is --</p> <p>17 And that was basically what the clearance 18 was, and so that was based on the 510(k) process for 19 general surgical mesh based on mechanics, mechanical 20 properties of mesh.</p> <p>21 So in some way that -- that actually hurt 22 the TVT products, TVT-S, because the FDA was using 23 basically a checklist. Oh, here's what the 24 mechanical properties are.</p> <p>25 And in this particular case with the TVT-S,</p>	<p style="text-align: right;">Page 133</p> <p>1 A. The biomaterial is a big one.</p> <p>2 Q. -- that would have applied to TVT-Secur.</p> <p>3 I'm not so much asking about what could FDA have 4 done differently within the existing structure.</p> <p>5 A. Okay. If we just talk about the process, 6 the biomaterials, in that you have polypropylene 7 implanted in women back before 1976, so it's a 8 pre-amendment product that nobody has really looked 9 at, has a long history of use in surgical mesh, but 10 because it was a pre-amendment product, nobody's 11 really looked at it, so that's part of the process.</p> <p>12 So we basically tied our biomaterials in the 13 United States to pre-1976 because it's much easier 14 for a manufacturer to use a pre-1976 material than 15 to go and develop a new material.</p> <p>16 And so inadvertently the 510(k) process has 17 held us to older technology or biomaterials, so 18 that's one of the big things.</p> <p>19 The other one is the process, the least 20 burdensome. Since 1997 -- yeah, 1997, they had -- 21 the FDA reviewers were required to use the least 22 burdensome method for industry to get clearance.</p> <p>23 And so, therefore, it limits what the FDA 24 can request in terms of, they can't request just -- 25 you know, if you have not requested it from somebody</p>

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<p style="text-align: right;">Page 134</p> <p>1 else, clinical data, you can't request it all of a  2 sudden from somebody else without support, so the at  3 least burdensome is another one in there.  4 The truthful and accuracy statement we have  5 there because the FDA is to assume that there's no  6 material fact not being provided because they sign a  7 certificate.  8 Well, you know, that isn't always the case.  9 The manufacturers haven't been providing the  10 information to the FDA. So those are three big  11 ones, the least burdensome, biomaterials, and what's  12 the third one?  13 Q. The truthful and accurate.  14 A. The truthful and accurate. And then MDUFA,  15 people have also looked at MDUFA in terms of having  16 to have something get done within 90 days.  17 Otherwise, the reviewers are held responsible if  18 they take longer. You could only ask for two  19 additional information rounds.  20 So those are things that put a lot of  21 pressure on the reviewer to get something done very  22 quickly.  23 Q. Are you critical of congress for those  24 features of the process, or are you critical of the  25 FDA for those features of the process?</p>	<p style="text-align: right;">Page 136</p> <p>1 understand it's your opinion that it was not a safe  2 and effective device from day one, and it should  3 never have been cleared.  4 Is that a fair statement?  5 A. Based on the information that they had, I  6 don't think they had sufficient information to show  7 that it would be substantially equivalent to the  8 Gynecare tape. That was what it was actually  9 cleared against. It wasn't actually cleared against  10 TVT-O or TVT.  11 I think the use of the CODMAN Dura Patch was  12 kind of iffy. That was not a good design thing.  13 And you could do it, but I don't think it was  14 actually tested to make sure that it would be --  15 hold in place.  16 Q. If the 510(k) process for TVT-Secur had been  17 different, do you believe the FDA would have reached  18 a different decision with regard to the clearance of  19 TVT-Secur?  20 A. No. I mean, I'm going to say that the  21 TVT-Secur is cleared. It was cleared. And so what  22 does that mean if Ethicon gets a clearance? It  23 means they have to have the device that actually  24 performs the way they described it in their 510(k),  25 and that's really where it all falls down.</p>
<p style="text-align: right;">Page 135</p> <p>1 MR. JONES: Objection.  2 THE WITNESS: Well, it would be both,  3 because some of those features were developed by the  4 FDA. The FDA developed the 510(k) process.  5 Congress actually thought the PMA would be used more  6 frequently. FDA really got into the 510(k) process,  7 so the 510(k) process has been developed internally  8 more or less.  9 The least burdensome actually came from  10 congress in terms of FDAMA in 1997, so that was  11 congress. The Medical Device User Fee Act was also  12 congress. So it's both of them.  13 BY MR. GAGE:  14 Q. All right. And would it -- is it fair to  15 say that you disagree with either congress or the  16 FDA on those issues that you have identified?  17 A. I don't disagree.  18 I mean, I just know from, having worked  19 there, that these are constraints. And when you  20 worked there, these are constraints that you had.  21 You just weren't allowed to ask for anything.  22 So am I complaining about them or what? I'm  23 just saying, these are the constraints that a  24 reviewer has to work with.  25 Q. All right. And with regard to TVT-Secur, I</p>	<p style="text-align: right;">Page 137</p> <p>1 If Ethicon did get clearance; therefore,  2 they needed to market the product that behaved the  3 same way that they said TVT-Secur would work. When  4 it doesn't work, then you're not marketing the  5 device that was cleared under the 510(k).  6 And so it's -- that's where your post-market  7 surveillance comes in. Once you realize it's not  8 working that way, you shouldn't be selling it.  9 Q. Maybe I misunderstood, but I thought that  10 your opinions with regard to TVT-Secur are  11 impacted -- strike that.  12 I understood that it is your opinion that  13 certain features of the 510(k) process allowed the  14 device like TVT-Secur to get clearance when it  15 should not get clearance under an appropriately  16 rigorous clearance process.  17 Is that your opinion?  18 A. I look at it as the risks that I'm seeing  19 and saying were foreseeable to Ethicon as the expert  20 in this design of this product. They should have  21 seen this.  22 It has nothing to do with the FDA. It's  23 more with Ethicon in terms of the CODMAN and the use  24 of these products.  25 Q. I know, but I'm trying to understand why you</p>



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<p style="text-align: right;">Page 138</p> <p>1 put in your expert report that the FDA's 510(k)  2 process has weaknesses.  3 A. It does.  4 Q. Have we discussed those weaknesses?  5 A. Right.  6 Just because you get 510(k) clearance  7 doesn't mean your device is going to work, and so  8 there are weaknesses. It's not a PMA approval  9 process or anything. It's -- it's -- but it has  10 limitations.  11 And the FDA can't ask for more information  12 unless they have certain key things to let them do  13 it. Yes, it's a weak -- it's got system problems,  14 but the issue is you can't market something that  15 doesn't behave the way it's cleared.  16 Q. Right.  17 A. So, you know, it's -- yes, indeed the FDA  18 cleared it, but the FDA cleared it, and so then --  19 the FDA clears devices that there is no device even  20 made. You're describing in your 510(k) what you're  21 going to sell.  22 Q. But as I understand it, the FDA -- it is  23 your opinion that the FDA cleared TVT-Secur under a  24 process that is flawed?  25 A. Yeah.</p>	<p style="text-align: right;">Page 140</p> <p>1 BY MR. GAGE:  2 Q. Okay. And have we identified the flaws in  3 the process that you believe impacted the clearance  4 decision for TVT-Secur?  5 A. Well, and also I didn't get to say about  6 the --  7 Q. Could you answer that?  8 A. Almost, almost.  9 Q. Have we discussed them?  10 A. Almost, except for one other thing.  11 Q. Okay.  12 A. And that would be the use of the Dura Patch.  13 That -- that really was able to be bridged because  14 it was already a cleared device.  15 So there was minimal requirement for the  16 company to provide anything to the FDA on that, and  17 so it's the bridging system, that if something is  18 cleared, you can bridge it for a new intended use,  19 and, yet, you may not have done clinical studies to  20 make sure that it's actually -- they did a sheep  21 study, but the sheep study is pretty inadequate, the  22 way it's designed.  23 Q. All right. And, Dr. Parisian, on -- in  24 paragraph 80, page 36 of your report, you have a  25 sentence that says, "To clear the 510(k) for</p>
<p style="text-align: right;">Page 139</p> <p>1 It has limitations to it, and so if --  2 somebody thinks there's a loss of testing, and  3 there's not. It's a limited system. There's  4 certain restrictions on the FDA.  5 FDA can only trigger and ask for certain  6 things if other things occur, so it's -- it's got  7 all kinds of pitfalls in it, but the bottom line is  8 you can't sell the product if it doesn't behave the  9 way you're cleared.  10 Q. And is it my understanding that in your  11 opinion there are only two organizational bodies  12 that could apply fixes or remedies to that 510(k)  13 process, and that is either congress or the FDA?  14 MR. JONES: Objection.  15 THE WITNESS: Well, if you're talking  16 about changing the laws, the congress is the one who  17 gives all the authority and the requirements. The  18 FDA tries to interpret the laws to fit what congress  19 says, but it is a flawed system.  20 It's not what -- people think that it's  21 perfect. But the bottom line is, you can't sell.  22 It's a prohibited act, not for the FDA but for the  23 manufacturer, to sell a product that doesn't behave  24 the way it's cleared.  25 ///</p>	<p style="text-align: right;">Page 141</p> <p>1 Ethicon, FDA's ODE reviewer requested no information  2 on the PROLENE Surgical Mesh Sling, but short-term  3 clinical or animal data from Ethicon to support the  4 feasibility that Ethicon's proposed TVT tape  5 procedure could be learned and used by surgeons to  6 implant a PROLENE sling with Ethicon's accessories  7 and instructions."  8 Do you see that?  9 A. Yes, sir. That's talking about TVT. That  10 was the history of TVT getting cleared.  11 Q. Okay.  12 A. Yeah. This was --  13 Q. I was trying to understand the import of  14 this sentence --  15 A. Oh.  16 Q. -- at two levels.  17 And my first question is, are you -- are you  18 critical here of the ODE reviewer for not requesting  19 additional information?  20 A. No.  21 And -- and the thing here is that ProtoGen  22 was out on the market, and they had to give  23 information -- ProtoGen was actually selling well at  24 the time TVT was cleared.  25 Q. Can you tell me, though, specifically what</p>



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<p style="text-align: right;">Page 142</p> <p>1 you mean when you said, "To clear the 510(k) for 2 Ethicon, FDA's ODE reviewer requested no information 3 on the PROLENE Surgical Mesh Sling, but short-term 4 clinical or animal data from Ethicon"? The sentence 5 sounds like the reviewer could have requested other 6 information but didn't. 7 And that's what I'm trying to ask. Is that 8 what you're suggesting? 9 A. Well, I'm saying -- I'm saying requested 10 would mean he didn't demand it, he didn't require 11 it. He could request it. 12 And so the ODE reviewer could have 13 requested, but since PROLENE is a cleared product, 14 PROLENE mesh, it would be unlikely that he could 15 force Ethicon to provide him stuff about the PROLENE 16 mesh sling, and so he could ask for something that 17 was new, which was the animal data about implanting 18 the tape sling would meet equipment. So there's 19 limitations as to what the FDA could request, and 20 I'm not saying require. I'm saying request. 21 Q. So is -- what I'm trying to understand is 22 what you're saying is he had the power to request 23 it, but he didn't? 24 A. No. He didn't have the power to request it 25 because Ethicon could have told him to go pound</p>	<p style="text-align: right;">Page 144</p> <p>1 it? 2 A. He could have requested, but he didn't that 3 I saw, and what he requested is what he could get. 4 Q. And we're not to read that sentence as 5 you're being critical of the ODE reviewer for not 6 making the request? 7 A. No. 8 Q. Why did you write it, then? 9 A. It's because it's describing the process, 10 that in terms of PROLENE, the FDA knows that it's 11 already approved as a mesh, so there's very limited 12 information you can ask about PROLENE mesh because 13 it's been marked since the pre-amendment time. 14 So he could request it, but he didn't, and 15 he could request animal data, which is what he did 16 request. And so he did get some animal data about 17 putting the kit, because that's a new safety issue. 18 PROLENE mesh is not a new safety issue, so it's 19 describing limitations to what FDA can request. 20 Q. And this would go back to one of the 21 weaknesses in the 510(k) system -- 22 A. That's right. 23 Q. -- that you identified earlier? 24 A. That's right. That was with the 25 biomaterials and being able to reference, you know,</p>
<p style="text-align: right;">Page 143</p> <p>1 sand. I mean, the thing is, they didn't ask for it 2 from ProtoGen, so he can't -- he can't require it. 3 He can request it. 4 Q. I understand. I have to -- 5 MR. GAGE: I got to move to strike the 6 answer. 7 BY MR. GAGE: 8 Q. My question is very specific. 9 A. Uh-huh. 10 Q. Are you critical of the ODE reviewer for 11 having the ability to request additional information 12 and not actually requesting it? That's my simple 13 question. 14 A. No, I'm not critical of the FDA reviewer, 15 because the FDA reviewer could request it nicely and 16 say, "Could you please give it to me?" And that's 17 what I'm saying. Not that he could require it. He 18 couldn't require it. 19 Q. Well, why did you point out that he 20 requested no information other than short-term 21 clinical or animal data? The sentence implies he 22 could have requested more. 23 A. He could have requested it, but Ethicon 24 wouldn't have to give it to him. 25 Q. I understand. But he could have requested</p>	<p style="text-align: right;">Page 145</p> <p>1 other devices that are cleared. 2 PROLENE mesh has been cleared, so there's 3 very limited information that an FDA can request. 4 Q. So would it be correct to say that the 5 weaknesses in the 510(k) process affected the 6 decision to clear TVT-Secur, not just in the context 7 of the 510(k) for TVT-Secur, but also in the 510(k) 8 process for all of the predicate -- 9 A. That's right. 10 Q. -- devices for TVT-Secur? 11 A. That's right. 12 Q. So the weaknesses of the 510(k) system with 13 regard to ProtoGen and TVT and TVT-O all fed into 14 additional weaknesses that manifested during the 15 review of the TVT-Secur 510(k), all of which to some 16 degree led to, in Dr. Parisian's opinion, a flawed 17 decision to clear TVT-Secur? 18 A. It wasn't the FDA's flawed decision. It was 19 just the process allows the product to get on the 20 market that may not be safe and effective. 21 Because when you look at a TVT-Secur, it 22 wasn't cleared on TVT or TVT-O. It was cleared 23 because they found a 510(k) for the Gyne Ideas tape, 24 and because they found a cleared 510(k) for its 25 small tape, FDA couldn't ask for clinical data.</p>

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<p style="text-align: right;">Page 146</p> <p>1 Dr. Herrera wanted 12 months clinical data, and it 2 totally negated what FDA could ask for when the 3 company found a predicate. 4 MR. AYLSTOCK: And you're down to about 5 eight minutes, just so you know. 6 MR. GAGE: I'm down to about eight 7 minutes? Okay. Thank you. 8 BY MR. GAGE: 9 Q. Have you looked at any expert report by 10 Dr. Thomas Mule? 11 A. No. 12 Q. Do you know who Dr. Thomas Mule is? 13 A. No. 14 Q. Okay. Dr. Parisian, with regard to this 15 deposition Exhibit 8, which was one of the documents 16 you handed me earlier, and I'm going to just kind of 17 come over and stand next to you as we look through 18 those documents. 19 As I understand it, these are documents that 20 you pulled off the FDA Web site or some other Web 21 site. Is that correct? 22 A. The FDA's Web site, yes, sir. 23 Q. What is the significance, if any, of 24 Deposition Exhibit No. 8 to your opinions with 25 regard to TVT-Secur?</p>	<p style="text-align: right;">Page 148</p> <p>1 kit as to how the instruments worked with the -- the 2 tape. 3 Q. Were the instruments for TVT-Secur brought 4 to the attention of the FDA in conjunction with 5 TVT-Secur's 510(k)? 6 A. I don't recall. I think they were in there. 7 But the point was that the FDA was not reviewing 8 them as kits in terms of functionality because when 9 you look at components like that, you're supposed to 10 look at the -- the human factors and stuff like that 11 in using it. 12 And so they weren't -- they were saying in 13 the FDA's memo in 2007, 2008, their internal 14 discussion, how did we get to a transvaginal 15 insertion? And so the FDA was kind of trying to 16 backtrack, and these instruments are essential to 17 putting these devices in blindly in the pelvis. 18 Q. I hate to backtrack on you and go back to 19 something we've already covered, but I just realized 20 I needed to cover it. 21 During the Garcia deposition -- I think it 22 was on page 68 of your deposition -- you said, and 23 I'm paraphrasing. I'm not attempting to quote you 24 exactly, so I would ask that we all not get hung up 25 on that.</p>
<p style="text-align: right;">Page 147</p> <p>1 A. You were asking me before about MDRs. The 2 FDA went and did MDRs, you know, up here in terms of 3 looking at the instruments and stuff. So there's a 4 lot of information in here about MDRs. 5 I would then rely on the MDA's database, 6 looking at the different companies, so -- and I 7 think they actually do talk about TVT-Secur in here 8 in some places. 9 The highlighting is mine. They're going 10 through, looking at -- because I think the 11 instruments also weren't looked at, and so that was 12 why the FDA is wanting to reclassify the instrument 13 because that's important in terms of putting these 14 products in. They weren't looked at as kits. 15 Q. And when we talk about instruments, we're 16 talking about the instruments that, in the context 17 of TVT-Secur, would have been provided along with 18 the actual mesh itself? 19 A. That's right. 20 And so they weren't getting reviewed as kits 21 where you would look at the functionality. They 22 were -- some people -- well, Johnson -- actually, 23 Ethicon was good. TVT, they did include the 24 instruments in TVT to begin with, but -- and then 25 they started kind of -- so you needed to look at the</p>	<p style="text-align: right;">Page 149</p> <p>1 But you essentially said that although your 2 disclosure didn't mention anything about MDR 3 reporting, you did an MDR search the night before 4 your deposition and found inconsistencies of what 5 you believe the company knew versus what was 6 reported in the MDRs. 7 You then said on page 71 that your computer 8 wasn't working well and you were not able to print 9 off all the reports. 10 And on page 73, you implied that you would 11 continue the project and go month by month and 12 gather the data that you needed to support your 13 opinion. 14 Do you have any recollection of that 15 testimony? 16 A. I remember the testimony, but I wasn't asked 17 to go ahead and do that, so that's not in the 18 report. 19 Q. Okay. So just to nail it completely solid 20 shut, is it correct that notwithstanding your 21 testimony and the limited comparison between the MDR 22 reporting and the MAUDE database that you testified 23 to -- testified about in Garcia, your earlier 24 testimony holds true -- that is, you do not intend 25 to provide an opinion in any federal case under this</p>

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<p style="text-align: right;">Page 150</p> <p>1 report that you've served in this case about an  2 analysis or comparison between what Ethicon knew or  3 didn't know with regard to product issue reports or  4 complaint reporting versus what's in the MAUDE  5 database?  6 A. I haven't been asked to do that.  7 Q. Okay.  8 A. And I think I was looking for trends at that  9 time, not specific failure to report, but I was  10 looking at the numbers that were being reported and  11 what I knew were the reports.  12 Q. Okay.  13 A. I think they were using company documents.  14 Q. Have you done any analysis, or have you  15 tried to determine the number of lawsuits that have  16 been filed with regard to TVT-Secur?  17 A. No.  18 Q. Have you tried to determine the number of  19 women who were implanted with the TVT-Secur?  20 A. No.  21 Q. Have you attempted to do any sort of an  22 analysis about -- have you done an analysis of any  23 lawyer advertising with regard to TVT-Secur?  24 A. No.  25 Q. Have you -- in your MDL reports, you have</p>	<p style="text-align: right;">Page 152</p> <p>1 opinions with regard to the weight or the pore size  2 of the mesh would be a function of your review of  3 the company documents on those issues?  4 A. Right. Because they're not out in the other  5 documents.  6 Q. Have you -- have you seen any medical  7 literature with regard to TVT-Secur that attributes  8 any adverse events to pore size or weight of the  9 mesh?  10 MR. JONES: Objection.  11 THE WITNESS: No, but it's PROLENE, the  12 mesh. And, actually, when I look at the literature,  13 I don't see the pore size usually stated. That was  14 why I have to use company docs.  15 BY MR. GAGE:  16 Q. Have you read Dr. Marty Weisberg's 2015 --  17 November 2015 deposition?  18 A. I have looked at it quickly, and that's why  19 you have that. Remember, I brought that because  20 it's not listed, I don't think, on --  21 Q. When did you receive that deposition?  22 A. I received it a couple days ago.  23 Q. So you received it for the first time after  24 you had written your MDL report. Is that correct?  25 A. Yes, sir.</p>
<p style="text-align: right;">Page 151</p> <p>1 got some opinions about alleged problems with  2 heavyweight small pore mesh.  3 Do you recall that?  4 A. Where are you going? Forty-eight or  5 something?  6 Q. It's somewhere around paragraphs 108 to 113.  7 A. Okay, yeah.  8 Q. But do you -- and I'm not going to ask you  9 the exact specifics.  10 A. Paragraph 108, is that the one you want,  11 where I have the list? And this is -- this is  12 coming from -- this is Ethicon's PowerPoint  13 presentation is what this is. It is not my list.  14 Q. Well, that is what I wanted to ask you  15 about.  16 Apart from reviewing the Ethicon documents,  17 did you conduct any additional analysis of other  18 documents, such as published medical literature, to  19 reach any opinions with regard to the weight or pore  20 size of the mesh?  21 A. Oh, when you saw my patent, I went and tried  22 to get the patent. I was trying to get that.  23 No, nothing else.  24 Q. All right. So what you know -- the  25 documents or the information that support your</p>	<p style="text-align: right;">Page 153</p> <p>1 Q. Do you intend to supplement, amend, or  2 modify your report based on that deposition?  3 A. I don't think so. I haven't been asked to.  4 I don't think I am.  5 Q. Have you read enough of the deposition to  6 know whether it supports or refutes any of your  7 opinions in your MDL Secur report?  8 A. It supports my opinions because I know like  9 Health Canada wanted them to update their labeling,  10 their TVT labeling. I have TVT labeling and they  11 wanted them to take out mild, moderate,  12 inflammation, so it supports my opinions.  13 All the changes that they made to the 2015  14 label they could have made at any other time. That  15 supports my opinions, so I think it supports it.  16 Q. Is it fair to say that you are -- is it fair  17 to say that the changes requested by Health Canada,  18 in your opinion, are woefully inadequate to make the  19 TVT-Secur IFU adequate?  20 MR. AYLSTOCK: Objection to form.  21 THE WITNESS: Well, I don't -- I mean  22 the bottom line --  23 BY MR. GAGE:  24 Q. Let me rephrase it.  25 A. Yeah.</p>

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<p style="text-align: right;">Page 154</p> <p>1 Q. Is it your opinion that the -- that the 2 recommendations from Health Canada are inadequate to 3 make the TVT-Secur IFU adequate? 4 A. Well, the Canadian came after the TVT-Secur 5 was off the market. It's the TVT family, so if we 6 talk about it in the family, it's still an 7 inadequate label. I think that's what you're asking 8 me. Do I think it's still an inadequate label. 9 Q. I could ask it -- 10 MR. AYLSTOCK: I think we're over the 11 time. 12 MR. GAGE: Let me just ask her a couple 13 more. 14 MR. AYLSTOCK: Okay. 15 MR. GAGE: Because I want to correct 16 that. 17 BY MR. GAGE: 18 Q. Is it your opinion that if Ethicon had made 19 the changes to the TVT-Secur IFU that Health Canada 20 recommended when the device was first launched on 21 the market, that that would still not make the 22 TVT-Secur IFU adequate, in your opinion? 23 A. Right, it wouldn't be adequate. It was not 24 adequate because the changes that were made are 25 fairly minor.</p>	<p style="text-align: right;">Page 156</p> <p>1 CERTIFICATE 2 3 I, ALISA SMITH, Registered Professional 4 Reporter, Arizona Certified Reporter, do hereby 5 certify that, pursuant to notice, the deposition of 6 SUZANNE PARISIAN, M.D. was duly taken on 7 March 8, 2016, at 1:34 p.m., before me. 8 The said SUZANNE PARISIAN, M.D. was duly 9 sworn by me according to law to tell the truth, the 10 whole truth, and nothing but the truth and thereupon 11 did testify as set forth in the above transcript of 12 testimony. The testimony was taken down 13 stenographically by me. 14 I do further certify that the above 15 deposition is full, complete, and a true record of 16 all the testimony given by the said witness. 17 18 19 20 Alisa Smith, RPR, AZ CR 50712 21 (The foregoing certification of this transcript does 22 not apply to any reproduction of the same by any 23 means, unless under the direct control and/or 24 supervision of the certifying reporter.) 25</p>
<p style="text-align: right;">Page 155</p> <p>1 It's still not -- in terms of the TVT-Secur, 2 the label is not adequate for TVT-Secur. 3 Q. Have you -- have you looked at any of the 4 documents? 5 A. Let me clarify. It would be better than 6 what they launched it with, but it is not adequate. 7 It still wouldn't be adequate today. 8 Q. Okay. All right. 9 MR. GAGE: I understand counsel is 10 calling me on my time. So like I'm sure they'll say 11 at every deposition, if I were allowed more time, I 12 would ask more questions, but as a understand it, 13 I've got a hard stop at three hours. 14 So the only thing I'll ask counsel on 15 the record before we go off is we do have to circle 16 back and close some loops on some things, but I 17 think we've all agreed to work in good faith to get 18 that done. 19 MR. JONES: Indeed. 20 MR. GAGE: Thank you. Deposition is 21 terminated. 22 (Deposition concluded at 5:06 p.m.) 23 24 25</p>	<p style="text-align: right;">Page 157</p> <p>1 INSTRUCTIONS TO WITNESS 2 3 Please read your deposition over carefully 4 and make any necessary corrections. You should state 5 the reason in the appropriate space on the errata 6 sheet for any corrections that are made. 7 8 After doing so, please sign the errata sheet 9 and date it. It will be attached to your deposition. 10 11 It is imperative that you return the 12 original errata sheet to the deposing attorney within 13 thirty (30) days of receipt of the deposition 14 transcript by you. If you fail to do so, the 15 deposition transcript may be deemed to be accurate 16 and may be used in court. 17 18 19 20 21 22 23 24 25</p>

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<div style="text-align: center; padding: 5px; margin-bottom: 10px;">ACKNOWLEDGMENT OF DEPONENT</div> <p>I, SUZANNE PARISIAN, M.D., do hereby acknowledge that I have read the foregoing pages, 5 through 155, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.</p> <p>_____</p> <p style="text-align: center;">SUZANNE PARISIAN, M.D.                      DATE</p> <p>Subscribed and sworn to before me this _____ day of _____, 20____.</p> <p>My Commission expires: _____</p> <p>_____</p> <p>Notary Public</p>																																																																																																																																																																																																																	